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Assessment and Documentation of Newborn Pain: An Intervention and Longitudinal Evaluation

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ASSESSMENT AND DOCUMENTATION OF NEWBORN PAIN:
AN INTERVENTION AND LONGITUDINAL EVALUATION

BY

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ABSTRACT

The framework that guided this study was Dorothea Orem’s Self Care Deficit Theory (2001) and the principles of andragogy (Knowles, 1998). This quasi-experimental study utilized a repeated measures design and retrospective, as well as cross-sectional, data to investigate the effectiveness of a comprehensive intervention for increasing the assessment documentation of newborn pain. Also of interest was the effect of the intervention on the frequency and documentation of nonpharmacologic newborn pain management.

The overall findings of this study, following the programmatic intervention, indicate that there was an increase in documentation of pain assessment following painful procedures. The study also showed an increase in the total number of pain assessments and nonpharmacologic interventions documented in the nurses’ notes. The results of the study were both statistically significant and of practical importance. There was an increase in the mean number of pain assessments, pain assessments following painful procedures, and nonpharmacologic interventions documented. These results of this study are also of clinical importance. The a priori effect size was set at 20%, based on the research literature. When examining the entire programmatic intervention (Time 0 versus Time 2) the effect size for documented pain assessment following procedures was 33.25%, and the effect size for documented nonpharmacologic interventions was 34.47%. The results support the use of a programmatic intervention to increase documentation of pain assessment after painful procedures and nonpharmacologic interventions by the nursing staff. Of the nurses in this study, 50% were greater than 41 years of age. An interesting Pearson correlation ($r = -2.52$) showed that as the number of years of nursing experience increased, the total number of NIPS documented decreased.
CHAPTER 1
INTRODUCTION

United States law prohibits the performance of even minor surgical procedures on animals without adequate pain relief (Improved Standards for Laboratory Animals Act, 1985). However, there are no federal or state laws that prevent minor surgical procedures on newborn humans without anesthesia. In fact, circumcisions, the most commonly performed surgical procedure on newborns, are routinely performed without adequate analgesia or anesthesia (Kraft, 2003). Research has shown that infants are capable of nociception at birth (Walden & Franck, 2003; Mitchell & Boss, 2002). In fact, their peripheral and central structures necessary for pain perception are present and function between the first and second trimester of development (Walden & Frank, 2003). Therefore, care providers have the responsibility to assess newborns’ level of pain accurately and consistently, and secondly to relieve this pain through appropriate measures. Above all, they must provide at least the same level of care afforded to animals and protect them from known painful experiences when possible.

The physiology of pain in newborns is basically the same as it is in adults. Noxious stimuli excite primary afferent fibers that transmit signals from the periphery to the dorsal horn of the spinal cord via primarily the A-delta and C fibers (Walden & Frank, 2003). Pain is a normal physiologic response. However, prolonged or frequent pain, such as the pain experiences during and after a circumcision, can have many negative effects on the newborn. Infants undergoing painful procedures experience physiologic and behavioral changes (Harrison, Evans, Johnston, & Loughnan, 2002).
Behavioral changes include crying, facial grimacing, and body movement. Physiological changes include an increase in heart rate, respiratory rate, and blood pressure, and changes in the levels of oxygen and carbon dioxide in the blood. In addition, infants experience biochemical, hormonal, and metabolic changes in response to painful stimuli (Halimaa, Vehvilainen-Julkunen, & Heinonen, 2001). Short term consequences of painful stressors may lead to sleep disturbances, feeding difficulties, and body temperature instability (Walden & Franck, 2003). In addition, studies indicate that painful experiences may have lasting effects on behavior and development (Mitchell & Boss, 2002; Walden & Frank, 2003).

Despite an increased awareness of pain in newborns over the past decade and recent efforts to improve pain management in this vulnerable population, studies indicate that pain management for infants is still inadequate (Alexander & Manno, 2003; Bildner & Krechel, 1996; Bookbinder, Rutledge, Donaldson & Pravikoff, 2002; Halimaa et al., 2001). Pain intensity and pain relief should be assessed and documented at regular intervals (Agency for Health Care Policy and Research [AHCPR], 1992; Joint Commission of Accreditation of Healthcare Organizations [JACHO], 2001). Pain assessment is a key step toward the recognition of pain and the use of routinely planned pain reduction strategies (AHCPR, 1992; Harrison et al., 2002). However, since the infant patient is unable to communicate verbally that they are experiencing pain; the nurse must rely on alternative methods to assess pain in this population. In an attempt to increase the documentation and reliability of pain assessment in the newborn patient, a number of pain assessment tools have been created based on behavioral cues that indicate pain (Gallo, 2003; Reyes, 2003). Pain assessment tools assist the nurse in objectively identifying and quantifying pain. These tools assist in evaluating the effect of measures taken to alleviate pain. Currently, however, there is not a universally accepted tool to assess neonatal pain (Walden & Franck, 2003; Gallo, 2003).

In addition to pain assessment, the use of nonpharmacologic pain interventions has also gained increased recognition as being a necessary component in neonatal pain management (AHCPR, 1992; Gallo, 2003; Kraft, 2003). Non-pharmacologic interventions can be useful in decreasing pain in the newborn. These interventions are key components in the management and prevention of neonatal pain (Stevens, Gibbons,
& Franck, 2000). Non-pharmacologic interventions include swaddling, rocking, non-nutritive sucking, and music therapy. Pain assessment and non-pharmacologic interventions must be utilized and documented in the infant’s chart (AHCPR, 1992; Gallo 2003).

**Statement of the Problem**

Adequate documentation of pain assessment and intervention is a key element in effectively managing pain in the newborn after painful procedures. It is the nurses’ responsibility to provide clear documentation that a pain assessment has been conducted to meet standards of best practice. To assess and manage pain effectively, pain levels must be assessed every time vital signs are taken and after painful procedures, such as circumcision, heel lances, venipuncture, and lumbar puncture (JCAHO, 2001). Routine assessment of pain increases the nurses’ knowledge about the infant’s condition and enhances the identification and relief of pain by utilizing nonpharmacologic interventions. Newborns are capable of nociception and feel pain and are, therefore, entitled to the same level of pain management and documentation of pain assessment and interventions as adult patients. Currently, despite an increase in awareness of the physiology of pain, the development of pain assessment tools and pain management guidelines, documentation of pain assessment and non-pharmacologic intervention remain inadequate for an estimated 1 million infants undergoing circumcision each year in the United States (American Academy of Pediatrics Task Force on Circumcision, 1999; Kraft, 2003). Inadequate assessment of pain and pain management for newborns compromises the quality, cost, and quality outcomes of their care and contributes to the needless suffering of newborns in pain (Rutledge & Donaldson, 1998).

**Significance of the Problem**

Despite evidence that infants experience pain, studies indicate that neonatal pain assessment, intervention, and documentation have been inadequate in the management of pain in this population (Bookbinder et al., 2002; Halimaa et al., 2001). The lack of adequate pain management has significant adverse physiologic, psychosocial, and developmental consequences (Mitchell & Boss, 2002). Painful stimuli can have short term and long term adverse effects on the nervous system of the newborn. A painful stimulus, such as circumcision, stimulates the release of catecholamines, glucagons, and
corticosteroids. The elevated catabolic state caused by pain can be damaging to an infant that has a higher metabolic state and less nutritional reserves than an adult. According to Walden and Frank (2003), pain causes anorexia that leads to poor nutritional intake, delayed wound healing, impaired mobility, sleep disturbances, withdrawal, irritability, and developmental regression. Body temperature instability has also been linked to painful stimuli (Walden & Frank, 2003). The most immediate danger related to pain in newborns is an increased risk of intraventricular hemorrhage that contributes to neonatal morbidity and mortality (Mitchell & Boss, 2002). Long term effects of painful stimuli may include altered pain perception, chronic pain syndromes, and somatic complaints. Repetitive pain in the preterm infant may be related to attention deficit disorders, learning disorders, and behavioral problems in later childhood (Mitchell & Boss, 2002).

The absence of documentation of pain assessment and non-pharmacologic interventions may be related to a limited understanding of neonatal pain assessment by nurses (Gallo, 2003). Halimaa et al. (2001) found that more than 90% of the health care professionals surveyed stated that they needed more knowledge about premature babies’ pain and its identification. This limited knowledge of non-pharmacologic methods to alleviate pain may influence the health care professional’s implementation and documentation of these interventions for infants during and after painful procedures. According to Gallo (2003), nurses routinely utilize comforting techniques, but rarely recognize them as non-pharmacologic interventions and provide limited documentation of the infant’s pain level or the interventions used to address it. Knowledge of normal growth and development, behavioral cues, subtle signs of pain, coupled with awareness of the painful procedures that contribute to pain provide the framework for effective pain management (Rutledge & Donaldson, 1998). Educational programs by an Advanced Practice Nurse (APN) can be used to increase the knowledge of pain and to increase the skills of health care professionals in the assessment and management of pain in the newborn. The APN can design an educational intervention that meets the mandated requirements by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The information provided by the evaluation of the programmatic intervention will be utilized by the APN to design future educational interventions for increasing documentation of pain assessment and nonpharmacologic interventions. In addition, the
APN can use the results of this study and evidenced-based research to establish pain management guidelines, policies, procedures, and protocols related to newborn pain management ensuring a high standard of care for all newborns. This strategy is meant to increase nurses’ awareness of pain in newborns and to increase documentation of pain assessment and nonpharmacologic interventions.

**Statement of the Purpose**

The purpose of this quasi-experimental study was to evaluate the effectiveness of a comprehensive intervention for increasing the assessment documentation of newborn pain as well as the frequency and documentation of nonpharmacologic newborn pain management following circumcision, heel lance, venipuncture, and lumbar puncture procedures. Positive outcomes may lead to the development of a standardized protocol which can then be shared through nationwide publication.

**Research Questions**

The following research questions guided the study methodology and data analysis procedures discussed in Chapter 3.

1. What is the effect of a programmatic intervention on the assessment documentation of newborn pain following circumcision, heel lance, venipuncture, and lumbar puncture procedures?
2. What is the effect of a programmatic intervention on the frequency and documentation of nonpharmacologic management?
3. What are the nurse characteristics associated with the assessment documentation of newborn pain following circumcision, heel lance, venipuncture, and lumbar puncture procedures?
4. What are the nurse characteristics associated with the use and documentation of nonpharmacologic pain management for newborns?

**Hypotheses**

The following are the hypotheses for this study:

1. There will be an increase in assessment documentation of newborn pain following circumcision, heel lance, venipuncture, and lumbar puncture procedures over time, following a programmatic intervention.
2. There will be an increase in the frequency and documentation of nonpharmacologic management of newborn pain.

**Operational Definitions**

For the purpose of this study the following terms have been defined.

*Nursing Characteristics:* Demographic and work-related descriptions of the attending nurses as documented on the demographic questionnaire created by the researcher.

*Educational Intervention:* A thirty minute PowerPoint presentation, created by Gallo (2003), focusing on physiological aspects of pain, assessment of pain, nonpharmacologic interventions, and documentation.

*Newborn/Infant/Neonate:* For the purpose of this study these terms mean the same; a human from birth to 28 days of life, as documented on the newborn admission record. For inclusion in this study the infant must be admitted to the Level I nursery, admitting infants 35 weeks gestation or greater as documented on the newborn admission record.

*Non-pharmacologic Interventions:* Any intervention, documented in the nurses’ notes, to alleviate pain that does not require a written order. This variable will be measured using a frequency count.

*Pain Assessment:* An unpleasant sensory and emotional experience associated with actual or potential tissue damage, as measured by the neonatal infant pain scale (NIPS) tool and documented in the nurses’ notes.

*Painful Procedures:* An invasive procedure, documented in the patient chart, in which the skin is penetrated including heel lance, venipuncture, lumbar puncture, and circumcision.

*Post-procedure:* A time period ranging between 1 and 2 hours following the time documented in the nurses’ notes for the procedure.

*Programmatic Intervention:* The implementation of a pain management policy for newborns consisting of two phases. The first phase consisted of the implementation of a pain management policy, the NIPS tool, and a pain algorithm. At this time, there was an educational in-service for the NIPS, provided by the Clinical Nurse Specialist and graduate nursing student. The second phase of implementation included an educational intervention provided by the researcher on the utilization of nonpharmacologic interventions and pain assessment after painful procedures.
Conceptual Framework

Dorothea Orem’s Self-Care Deficit Theory (2001) and Malcolm Knowles’ Adult Learner Theory (1998) were selected to comprise the framework of this study. Orem’s theory focuses on the nurse’s role in facilitating the care of those individuals that have limitations in carrying out their own self care demands, and provides a framework to identify patients that are in need of nursing services (Orem, 2001). In Orem’s model the nurse is an active participant in the care of the patient. By utilizing the principles of the adult learner, nurses can enhance their knowledge base and positively influence the health of their patients (Grant, Anderson, Ritchey & Gold, 1996).

Dorothea Orem’s Self-Care Deficit Theory

The foundation of the Self-Care Deficit Theory is that all individuals have self-care needs. Adults possess the ability to meet their self-care needs by employing their self-care agency. Self-care is therapeutic when it meets self-care demands and contributes to human structural and functional integrity. However, when a self-care demand is greater than the individual’s power of self-care agency, a self-care deficit exists. Orem (2001) stipulates that the need for nursing services is legitimate when the person has self-care or dependent care deficits. In the newborn population, the need for nursing is validated because the self-care agency of the neonate is not fully operative to meet their self-care demands, and the self-care deficits exceed the knowledge and abilities of the dependent-care agent. The role of the nurse changes over time as the needs of the infant and dependent-care agent evolve. Orem described three nursing systems: (a) wholly compensatory; (b) partly compensatory; and (c) supportive-educative. When dealing with newborns, the nurse must often provide more than one nursing system. In general, the nurse should provide supportive-educative interventions to the dependent care agent (Tolentino, 1990).

Self-care requisites are formulated insights about the actions needed in the regulation of individual’s functioning and development. Orem (2001) describes three categories of self care requisites: universal, developmental, and health-deviation self care requisites. There are eight universal self-care requisites that maintain the conditions necessary for the integrity of human function and structure. They represent the needs that are essential for every person. Developmental self-care requisites address needs
associated with human development. Health deviations self-care requisites exist when a person is ill or injured.

According to Tolentino (1990), the nurse can utilize Orem’s theory as a guide to determine the following: (a) the therapeutic self-care demand; (b) the potential to provide self-care; (c) the nursing system to be utilized; (d) the plan of care based on the selected nursing system; and (e) the nursing diagnoses based on self-care deficits of the newborn and the dependent-care agent. Tolentino (1990) theorized that infants have signaling cues, such as changes in behavior and crying, that assist the dependent-care agent in meeting the infant’s needs. These signaling cues are an early manifestation of self-care behaviors. An awareness of the neonate’s signaling actions can help the nurse respond to the infant’s self-care needs.

Malcolm Knowles: Adult Learner Theory

An educational intervention was provided for the nurses that will enhance their ability to interpret and respond to the signaling cues that the infant uses related to pain. Careful attention will be given to ensure that the education intervention utilizes the learning concepts described by Malcolm Knowles to educate the adult learner. According to Knowles (1980), an andragogical approach should be utilized when educating the adult learner. When utilizing this approach, there are several assumptions that must be made about adult learners: (a) they are self directed; (b) they can utilize life experiences as a resource for learning; (c) they must perceive a need to know; and (d) they are problem-centered and interested in immediate application of knowledge (Knowles, 1998). These assumptions will guide the design and implementation of the educational intervention for this study.

Knowles (1998) described the assumptions of the andragogical approach to adult education. Adults need to know why they need to learn something before they expend the energy to learn it. Adult learners have a self-concept of being independent-learners, can direct their own learning, and are responsible for their own decisions. They resent situations in which they feel others are imposing their will upon them. Adults bring to an educational session life experiences that inhibit or enhance their learning experience. Adults become ready to learn those concepts they feel they need to know and or need to utilize for real life situations in order to fulfill their role in society. Adults are life-
centered, task-centered, and/or problem-centered in their orientation to learning. Adults are motivated to learn when it will help them perform tasks or deal with problems in real life situations. Adult learners are generally more internally motivated, than externally motivated.

The researcher attempted to enhance the participants’ awareness of the “need to know” in the invitational letter presented to each nurse. The letter included the purpose of the study and described the benefits and risks of the research. The format and time obligation of the participants was also explained. Every nurse was given an invitation to participate in the educational course, and only those nurses that had a desire to participate attended the session. By presenting real life scenarios, the educator was able to aid the learner in applying the concepts to situations that occur in real life. The educator made the assumption that the nurses that came to the educational session were motivated to learn based on their willingness to participate in an educational intervention that was strictly voluntary. Furthermore, the review of the literature supported the need for an educational intervention. Halimaa et al. (2001) found that neonatal nurses desired additional information and education regarding neonatal pain assessment and nonpharmacologic interventions.

**Assumptions**

During the course of this study, the researcher made several assumptions about the data collected:

1. Knowledge deficits exist regarding newborn pain physiology and pain assessment tools and these deficits influence the nurses’ assessment and documentation of pain assessment in the newborn.
2. The nurses have knowledge deficits regarding nonpharmacologic interventions and these deficits influence the nurses’ implementation and documentation of nonpharmacologic interventions.
4. The nurse will document pain assessment every time an assessment has been conducted.
Limitations

There are several limitations that have been identified in this study. The generalizability of the study will be limited since a sample will be used to represent the target population. Charts will be reviewed retrospectively over a period of approximately one year. Since these comparison groups will not be identical, it will be difficult to implement an exact replica of this study. In addition, the study relies on the belief that a change in knowledge will result in a change in behavior.

Summary

In summary, newborns that undergo painful procedures are entitled to the same level of pain assessment and relief as the adult patient. Despite the development of tools to assess neonatal pain, the medical community has not applied a universal tool to use on all newborns (Gallo, 2003). Due to the subjective nature of the pain assessment tools, and the healthcare professional’s knowledge of pain in this population, pain assessment in newborns is still often inadequate (Alexander & Manno, 2003; Bildner & Krechel, 1996; Bookbinder et al., 2002; Halimaa et al., 2001). Nonpharmacologic interventions should be implemented by the nurse to enhance pain management, and should be documented in the patient’s chart (Franck & Walden, 2003, Gallo, 2003; Kraft, 2003). Without documentation in the infants’ chart of pain assessment and non-pharmacologic interventions that were implemented it is unclear how often these interventions are utilized. Educational programs increase the awareness and skills of nurses in the assessment and management of pain in newborns (AHCPR, 1992; Gallo, 2003; Howard & Thurber, 1998). To manage newborn pain adequately, pain assessments should be conducted every time vital signs are taken and during and after painful procedures such as a circumcision, heel lance, venipuncture, and lumbar puncture (JCAHO, 2001). The newborn has the innate right to accurate pain assessment and pain management to avoid needless suffering and potential short and long term consequences of untreated pain (Mitchell & Boss, 2002). A comprehensive review of the literature will be presented in Chapter 2.
CHAPTER 2
REVIEW OF THE LITERATURE

This study focused on documentation of pain assessment and nonpharmacologic interventions for infants following a programmatic intervention on pain pathophysiology, pain assessment, nonpharmacologic intervention, and documentation. A theoretical review illustrated the appropriateness of using Dorothea Orem’s Self Care Deficit Theory and Malcolm Knowles’ Adult Learning Theory to guide this study. The physiology of pain, responses to pain, and adverse consequences of pain are also discussed. In addition, the literature review explored the following areas: (a) documentation of pain assessment and nonpharmacologic interventions; and (b) the recommendations regarding staff education of pain assessment and nonpharmacologic interventions. This chapter is organized into two sections: a theoretical review and an empirical review of the literature.

Theoretical Review

Dorothea Orem: Self Care Deficit Theory

The self-care deficit theory of nursing includes the following concepts: (a) self-care/dependant-care; (b) self-care agency/dependent care agency; (c) therapeutic self-care demand; (d) self-care deficit; and (e) nursing agency (Orem, 2001). All adults possess the inherent ability to meet their own needs for survival, this is self-care. Furthermore, these adults possess the power to meet the needs of their children (dependent-care). The action verb that describes the ability to engage in this behavior is called self-care agency when done for self and dependent-care agency when done for a child. There are individuals and situations where self-care agency and dependent-care agency are not sufficient to meet the therapeutic self-care demands of the individual or their dependent. This results in a self-care deficit (Orem, 2001).

The Self-Care Deficit theory provides a framework to identify patients that are in need of nursing services. A proposition of the theory stipulates that the need for nursing
service is legitimate when the person has self-care or dependent care deficits. A person has a self-care deficit when the self-care demand is greater than the individual’s power of self-care agency. Self-care is the activities initiated and performed for the purpose of maintaining life, health, personal development, and well being. Self-care is therapeutic when it contributes to structural and functional integrity, developmental processes, and health and well being. Therapeutic self-care demand is the summation of care measures necessary at specific times or over a duration of time for meeting all of an individual’s known self-care requisites (Orem, 2001). Therapeutic self-care demands are calculated by identifying the self-care requisites and the frequency of actions necessary to meet the individual’s universal and developmental requisites, and any health deviation requisites if applicable (Dennis & Jesek-Hale, 2003). Additional information that needs to be assessed includes identification of factors that are unique to that individual, and are termed basic conditioning factors. Orem (2001), describes ten basic conditioning factors, which can inhibit or enable actions for meeting self-care requisites. Orem specifies three basic conditioning factors that must always be considered: (a) age; (b) developmental state; and (c) health state.

Self-care requisites are formulated insights about the actions needed in the regulation of individual’s functioning and development. Orem (2001) describes three categories of self care requisites: universal, developmental, and health-deviation self care requisites. There are eight universal self-care requisites that maintain the conditions necessary for the integrity of human function and structure. They represent the needs that are essential for men, women, and children. The eight universal self-care requisites include: (a) maintaining sufficient intake of air, water, food and nourishment; (b) managing care of elimination; (c) maintaining a balance between activity and rest, solitude and social interactions; (d) prevention of hazards to life, functioning and well being; and (e) the promotion of human functioning and development in social groups in accord with human potential, limitations, and normalcy (Orem, 2001).

Developmental self-care requisites address needs associated with human development. There are 2 basic categories of developmental self-care requisites. The first are requisites that are met by the dependent-care agent in the early stages of life. These include activities that promote life and human functioning and promote progression to a
higher level of development. The second type addresses those activities that demand the deliberate involvement of self in the process of development (Orem, 2001). Dennis and Jesek-Hale (2003), concur that no such conditions or events associated with Type 2 developmental self-care requisites exist for normal newborns. Type 2 developmental self-care requisites may need to be considered for infants with special needs and or conditions, such as cleft lip and palate (Dennis & Jesek-Hale, 2003).

Health deviations self-care requisites exist when a person is ill or injured. Dennis and Jesek-Hale (2003), concluded that when considering a population of normal newborns health deviations self-care requisites do not apply, since no health care deviations exist in this population.

Dorothea Orem’s Self Care Deficit Theory was used by Tolentino (1990) as a model for care in a neonatal intensive care-unit. The author utilized the model to assist the nurse in meeting the self-care deficits of the infant. The basis of this theory is that all individuals have self-care needs. Ideally, the individual is able to meet those needs. When a self-care demand is greater than the individual’s ability to meet that need, a self-care deficit exists. Newborns have many self-care deficits. A parent or guardian often assists the newborn in meeting self-care demands and is referred to as a dependent-care agent. If needs are more than those which the newborn and the dependent-care agent can handle, then nursing must assist in meeting self-care demands (Tolentino, 1990).

According to Tolentino (1990), the nurse can utilize Orem’s theory as a guide to determine the following: (a) the therapeutic self-care demand; (b) the potential to provide self-care; (c) the nursing system to be utilized: (d) the plan of care based on the selected nursing system; and (e) the nursing diagnoses based on self-care deficits of the newborn and the dependent-care agent. When caring for a newborn the nurse must evaluate the strengths and weaknesses of three agents: the newborn, the dependent-care agent, and the nurse. Tolentino (1990) theorized that infants have signaling cues, such as changes in behavior and crying, that assist the dependent-care agent in meeting the infant’s needs. These signaling cues are a manifestation of self-care behaviors. An awareness of the neonate’s signaling actions can help the nurse respond to the infant’s self-care needs. The nurse can then design a plan of care for the infant that: (a) incorporates the self-care potential of the neonate including the neonate’s unique reactions to positive and negative
stimuli; and (b) facilitates the development of the dependent-care agent. Integrating nonpharmacologic interventions into care giving promotes the infant’s own coping abilities. In the newborn population, the need for nursing is validated because the self-care agency of the neonate is not fully operative to meet their self-care demands, and the self-care deficits exceed the knowledge and abilities of the dependent-care agent. The role of the nurse changes over time as the needs of the infant and dependent-care agent evolve. Orem described three nursing systems: (a) wholly compensatory; (b) partly compensatory; and (c) supportive-educative. When dealing with newborns, the nurse must often provide more than one nursing system. In general, the nurse should provide supportive-educative interventions to the dependent care agent (Tolentino, 1990).

Malcolm Knowles: Principles of Andragogy

According to Knowles (1998), an approach of andragogy should be utilized when educating the adult learner. Knowles viewed adults as autonomous and growth-oriented. When utilizing this approach, there are several assumptions that must be made about adult learners: (a) they are self-directed; (b) they can utilize life experiences as a resource for learning; (c) they must perceive a need to know; (d) they are problem-centered and interested in immediate application of knowledge; and (e) they are internally motivated (Knowles, 1998). These assumptions will guide the design and implementation of the educational intervention for this study. The participants will be given a clear purpose for the education session and practical applications for course content.

Adults need to know why they need to learn something before they expend the energy to learn it. One of the tasks of the educator is to enhance the learners’ awareness of the “need to know.” The educator should demonstrate the value of the learning in improving the effectiveness of the learners’ performance. The need to know includes: (a) why learning is important; (b) how learning will be conducted; and (c) what learning will occur (Knowles, 1998). The researcher attempted to enhance the participants’ awareness of the “need to know” in the invitational letter presented to each nurse. The letter included the purpose of the study and described the benefits and risks of the research. The format and time obligation of the participants was also explained. In addition, Knowles (1998) recommended that adults be active in diagnosing their learning needs
and designing the course content. Due to the nature of this inquiry, such was not possible.

Adult learners have a self-concept of being independent-learners, can direct their learning, and are responsible for their own decisions. They resent situations in which they feel others are imposing their will upon them (Knowles, 1998). The nurses were not forced into participating in the educational intervention, and were free to leave without penalty at any point during the session. Every nurse was given an invitation to participate in the educational course, and only those nurses that had a desire to participate attended the session.

The roles of the learners’ experiences must also be considered. Adults bring to an educational session life experiences that inhibit or enhance their learning experience. The benefit of this life experience is that adults can contribute to group discussion and problem-solving simulations. The researcher incorporated real life scenarios into the educational session and kept the presentation informal to encourage group discussion. Participants were encouraged to ask questions and to offer suggestions. A problem-solving exercise was also included in the presentation. The negative effect of this life experience is the tendency to develop biases, habits, and presumptions that tend to decrease the receptiveness to new ideas and approaches to a problem. This is an obstacle that the educator must recognize when educating adult learners (Knowles, 1998).

The readiness to learn must also be considered. Adults become ready to learn those concepts they feel they need to know and or need to utilize for real life situations in order to fulfill their role in society. The facilitator of learning can induce readiness to learn through exposure to best practice and stimulation of interest (Knowles, 1998) . Again, every nurse on the unit was given an invitation to participate in the study. Only those nurses that had a desire to participate attended the session. By conducting a thorough review of the literature it was found that neonatal nurses desire additional information and education regarding neonatal pain assessment and nonpharmacologic interventions.

The orientation of learning must also be evaluated and considered by the educator. Adults are life-centered, task-centered, or problem-centered in their orientation to learning. Adults are motivated to learn when it will help them perform
tasks or deal with problems in real life situations. They are interested in immediate applications of knowledge (Knowles, 1998). By presenting real life scenarios, the educator is able to aid the learner in applying the concepts to situations that occur in real life.

Motivation to learn must also be evaluated. Adult learners are generally more internally motivated, than externally motivated. Internal motivators include self-esteem, quality of life, and personal satisfaction (Knowles, 1998). The educator makes the assumption that the nurses that came to the educational session were motivated to learn based on their willingness to participate in an educational intervention that was strictly voluntary.

In 1998, Knowles described a method of designing and managing learning activities for the adult learner. Knowles explained that the process of designing and operating learning activities involves the following phases: (a) setting a climate for change; (b) establishing a structure for mutual planning; (c) diagnosing needs for learning; (c) formulating objectives for learning; (d) designing a pattern of learning experiences; (e) managing the execution of learning experiences; and (f) evaluating results and rediagnosing learning needs. According to Knowles, for an educational intervention to have the maximum effect the researcher must promote an environment conducive to learning. This includes the physical environment such as lighting and temperature. This also includes the psychological environment. This addresses the learners’ perception of mutual respect and mutual responsibility. It is an environment that promotes collaboration and is supportive and caring. The emphasis should be on learning (Knowles, 1998). The researcher utilized these key elements to foster an environment to facilitate learning.

Responses to Painful Stimuli

Infants have the neurological capacity to perceive pain at birth. The peripheral and central structures necessary for pain perception are present and function between the first and second trimester of development. Functional maturation of the fetal cerebral cortex has been demonstrated by: (a) the electroencephalogram patterns and cortical evoked potentials; (b) measurement of cerebral glucose use that demonstrates increased metabolic rates at the sensory areas of the brain, and (c) the well defined periods of sleep
and wakefulness that are regulated by cortical function at 28 weeks gestation. The newborn possesses a developed hypothalamic pituitary adrenal axis and can mount a sympathetic nervous system response with the release of catecholamines and cortisol. Cortisol and endorphin release have been demonstrated in 23 to 34 week old fetuses (Walden & Frank, 2003).

The physiology of pain in newborns is basically the same as it is in adults. Noxious stimuli excite primary afferent fibers that transmit signals from the periphery to the dorsal horn of the spinal cord. A-delta and C fibers are primarily responsible for the transmission of pain impulses. However, in newborns transmission of pain impulses primarily occurs along the C fibers and in adults the A-delta fibers primarily transmit pain. In newborns, less precision occurs in pain signal transmission in the spinal cord, and descending inhibitory neurotransmitters are lacking. Therefore, the newborn may perceive pain more intensely than adults because the descending control mechanisms are immature (Walden & Frank, 2003).

Pain is a normal physiologic response. However, prolonged or frequent pain can have many negative effects on the newborn. Painful stimuli can have short term and long term adverse effects on the nervous system of the newborn. Infants undergoing painful procedures experience physiologic and behavioral changes. Behavioral changes include crying, facial grimacing, and body movement. Physiological changes include an increase in heart rate, respiratory rate and blood pressure, and changes in the levels of oxygen and carbon dioxide in the blood. In addition, infants experience biochemical, hormonal, and metabolic changes in response to painful stimuli (Halimaa et al., 2001). A painful stimulus causes the release of catecholamines, glucagons, and corticosteroids. The elevated catabolic state caused by pain can be damaging to an infant that has a higher metabolic rate and less nutritional reserves than an adult. According to Walden and Frank (2003), pain contributes to anorexia that leads to poor nutritional intake, delayed wound healing, impaired mobility, sleep disturbances, withdrawal, irritability, and developmental regression. Body temperature instability has also been linked to pain. The most immediate danger related to pain in newborns is an increase in intraventricular hemorrhage that contributes to neonatal morbidity and mortality (Mitchell & Boss, 2002). Long term effect of painful stimuli may include altered pain perception, chronic pain
syndromes, and somatic complaints. Repetitive pain in the preterm infant may be related to attention deficit disorders, learning disorders, and behavioral problems in later childhood (Mitchell & Boss, 2002).

There are several routinely performed painful procedures performed on the newborn. These include heel lance, venipuncture, lumbar puncture, and circumcision (Gallo, 2003). The most controversial of these procedures is circumcision. Circumcision remains the most common surgical procedure on newborn males in the United States despite the 1999 American Academy of Pediatrics policy statement indicating that routine neonatal circumcision is not medically necessary. Circumcision is the surgical removal of the skin covering the end of the penis of the male (Geyer, Ellsbury, Kleiber, Litwiller, Hinton, & Yankowitz, 2002). Despite an increased awareness of neonatal pain, many health care providers still perform neonatal circumcision without adequate analgesia or anesthesia. Other providers attempt to relieve pain by using single treatment modalities, which only partially relieves the pain associated with circumcision. Recent recommendations regarding circumcision pain management include using a combination of analgesia and local anesthesia to provide the most effective means to relieve pain related to circumcision (Kraft, 2003).

**Documentation of Pain Assessment and Nonpharmacologic Interventions**

Successful pain management includes each of the following key components: (a) accurate pain assessment, (b) pain alleviation methods, such as nonpharmacologic interventions, and (c) documentation of the pain assessment and methods utilized to alleviate pain in the medical record (Halimaa, 2003). It is difficult to separate these components since pain management is a process that incorporates all three. Systematic pain management requires documentation of the entire pain management process from assessment to intervention (Halimaa, 2003). Pain management is the obligation of all healthcare professionals, and all patients, including newborns, have a right to pain assessment, adequate intervention, and follow-up (Curtiss, 2001).

In recent years, pain in infants and children has gained increased attention. Historically, there were many misconceptions and a lack of understanding surrounding pain physiology in newborns. Pain management in the neonate population was rarely considered, because of the misconception that infants had immature nervous systems and
were incapable of experiencing pain. The AHCPR recognized the need for improvement in pain assessment in infants and children and made recommendations for healthcare practitioners (AHCPR, 1992). Pain assessment and documentation have also been mandated by regulatory agencies. The Joint Commission on Accreditation of Healthcare Organization (JCAHO), requirements were established for a pain assessment every time vital signs are taken, and before and after painful procedures (JCAHO, 2001). However, despite this increased awareness of neonatal pain, studies indicate that pain management for infants remains less than optimal (Alexander & Manno, 2003; Bookbinder et al., 2002; Halimaa et al., 2001).

Documentation of pain intensity and pain relief is vital in the recognition of pain and the use of routinely planned pain reduction strategies and leads to effective pain management (Harrison et al., 2002). This increases the health care professionals’ knowledge of the infant and optimizes pain assessment and management. Documentation can also increase communication among caregivers (Rutledge & Donaldson, 1998). Several tools have been created and clinically tested. However, information is lacking regarding implementation of these tools into clinical practice (Gallo, 2003). Despite evidence that infants, indeed, experience pain, and the development of tools to assess pain, infant pain management documentation remains inadequate (Bookbinder et al., 2002; Gallo, 2003). Advanced practice nurses (APNs) serve as patient advocates by recognizing this need, and assisting institutions in the implementation of pain assessment tools. Advanced practice nurses can assist in reviews to assure adherence to pain assessment, intervention, and documentation standards. In addition, the APN can assist in the creation of pain management policies and procedures to meet the standards of best practice (White, 1999).

Nonpharmacologic interventions can be useful in decreasing pain and distress in infants. It is recommended that nonpharmacologic interventions be used for minor procedures before progressing to pharmacologic interventions (AHCPR, 1992). Nonpharmacologic interventions, as defined by Gallo (2003), include repositioning, swaddling, kangaroo care, light massage, use of a pacifier, or breast/bottle feeding. Many researchers recommend that a multimodal approach, utilizing both pharmacologic, and nonpharmacologic interventions to pain management during painful procedures is the
most effective means to manage newborn pain (Geyer et al., 2002; Kraft, 2003; Malnory, Johnson, & Kirby, 2003). The effectiveness of pain management cannot be evaluated when there is a lack of documentation of follow-up pain assessment after painful procedures and lack of follow-up pain assessment following nonpharmacologic interventions (Reyes, 2003). Salantera, Lauri, Salmi, and Helenius (1999) found that nurses’ characteristics such as age, knowledge, experience, and attitudes and beliefs influence their knowledge of pain and implementation of interventions to alleviate pain.

In 1996, Bildner and Krechel conducted a study to increase staff nurse awareness of postoperative pain management in the neonatal intensive care (NICU). The study focused on the importance of having effective pain management in the postoperative period. Several barriers to effective and appropriate pain management were identified in the NICU by a multidisciplinary team: (a) Inadequate knowledge base of nurses/physicians; (b) Lack of objective assessment tools to measure pain; (c) Inadequate documentation of pain and pain management. The authors noted that the lack of pain documentation in the nurses’ charting made it difficult to evaluate assessments and interventions. Once these barriers were identified the multidisciplinary team developed an action plan to address these barriers to effective pain management. A pain management team, including a neonatal clinical nurse specialist and an oncology clinical nurse specialist, was identified to address pain issues. The goal of the team was to educate the staff nurses and to establish a standard of care for pain management. The next step in the process was to adopt an objective tool to measure pain. The team selected the CRIES (Crying, Requires oxygen, Increased vital signs, Expression, and Sleepless) tool. The team provided several poster in-services for the NICU staff that included the following topics: (a) indicators of irritability/agitation in the neonate; (b) The neonatal pain response; (c) use of medication for pain; (d) how to use the CRIES postoperative assessment tool. These poster presentations were supplemented by one-on-one consultation and discussion. The pain education was then built into the orientation program for all future nurses. Based on observation the authors concluded that the educational intervention was successful. Chart reviews indicated that the nurses more accurately documented their assessment of neonatal pain. The final barrier was the documentation of pain in the nurses’ notes. In the past, there was a high degree of
variability in the documentation of pain. The pain management team created and implemented a new flow sheet. The sheet included space for 24 hours’ worth of hourly pain assessments. If a CRIES score indicated pain, the score was circled, and the nurse entered a narrative description of the pain assessment, intervention, and the response to the intervention. Before finalizing the pain assessment form, a trial form was used for a period of time. The nurses were able to make suggestions and to have input into the final form (Bildner & Krechel, 1996).

*Educational Interventions*

Research indicates that staff education regarding pain pathophysiology, assessment, and management is a key element in the successful implementation of an effective pain assessment program (American Academy of Pediatrics, 2000; Collins, 1999; Howard & Thurber, 1998; Rutledge & Donaldson, 1998). There are several methods that can be utilized to provide continuing education to nursing staff. For example: in-services, conferences, and videotapes (Collins, 1999). Ideally the nurse should be an active learner and seek out educational opportunities about pain management. (Collins, 1999). As previously mentioned, a study conducted in 1996, identified three key barriers to effective and appropriate pain management. The first barrier was inadequate knowledge about pain by nurses and physicians. The second barrier was the lack of objective assessment tools to measure pain. The final barrier identified was the inadequate documentation of pain assessment and pain management (Bildner & Krechel, 1996). Staff education should include information about the short and long-term consequences of pain, and the differences of pain expression between term and preterm infants (Howard & Thurber, 1998). According to Gallo (2003), education programs must include physiological aspects of pain, assessment of pain, nonpharmacologic interventions, and documentation. Gallo (2003) concluded that inadequate knowledge results from insufficient education about pain in nursing programs. In addition, education enables the health care professional to recognize that a baby is experiencing pain and enables the caregiver to employ methods to alleviate pain (Halimaa et al., 2001). Howard & Thurber (1998) indicated that more in-depth education on pain recognition and interpretation of pain cues are needed for health care providers. Nurses with inadequate knowledge about pain may not successfully identify pain or may
underestimate the pain experienced by the newborn (Halimaa, 2003). The advanced practice nurse can provide education for staff nurses and other healthcare providers. In addition, the role of the advanced practice nurse is to provide clinicians with current education, training, and evidence-based research. In addition, to ensure quality and consistency in the treatment modalities, and to reduce variances in clinical practice, a multidisciplinary evidence-based protocol should be implemented to manage the pain associated with neonatal circumcision (Kraft, 2003).

Gallo (2003) implemented the Neonatal Infant Pain Scale (NIPS) for newborn pain assessment in a southern California hospital. NIPS was introduced throughout the hospital. The study focused on the implementation process for 125 labor and delivery nurses in a large women’s facility. During the initial phase of the educational intervention, the advanced clinicians were educated in the use of the NIPS. A 30-minute presentation was created that focuses on the physiologic aspects of infant pain, the NIPS tool, and documentation of nonpharmacologic interventions. Nonpharmacologic interventions were reintroduced, with an emphasis on documentation. During the second phase of implementation, the remainder of the staff was provided education by the advanced clinicians. This was accomplished through in-service programs, bedside teaching, and viewing the NIPS video created by the researcher. The final phase of implementation was assuring adherence. Sixty days after the original education session, an informal chart review was conducted. Results indicated that use of the NIPS by the nursing staff was 27%, especially after invasive procedures and documenting interventions. A second chart review was conducted 1 year after implementation. The chart review revealed a 65% adherence rate for a NIPS score with routine vital signs. The documentation of a pain score after a procedure was 60%, and for interventions was 55% (Gallo, 2003).

**Empirical Review**

*Dorothea Orem: Self Care Deficit Theory*

Lenatsch (1999) conducted a study that evaluated the knowledge, attitudes, treatment practices, and health behaviors of nurses regarding blood cholesterol. This study supports the use of Dorothea Orem’s Self Care Theory as an effective framework in identifying knowledge deficits and promoting a supportive-educative system to assist
patients in meeting self-care demands. The researcher applied Orem’s theory to the study by concluding that the attitudes, health behaviors, and knowledge of the nurses influence their treatment practices and client teaching. The study included 42 registered nurses that were randomly selected to participate in the study. Each participant completed a 48-item questionnaire developed by the National Heart, Lung, and Blood Institute. Responses to the questionnaire were analyzed using descriptive statistics. The results of the study indicated that barriers to change and lack of knowledge existed about blood cholesterol. Only 10% (13) of the participants answered “strongly agree” feeling they were prepared to provide diet counseling to clients, indicating a knowledge deficit in this area for the remaining 90% (29) of the participants. The researcher recommended continuing education courses to provide education to enhance nurses’ knowledge of cholesterol management, which would enhance the supportive-educative relationship between the nurse and the patient (Lenatsch, 1999).

Malcolm Knowles: Principles of Andragogy

Grant et al. (1996) conducted a study to evaluate the effectiveness of a community-based educational program for cancer nursing. The researchers utilized Malcolm Knowles’ principles of andragogy as a framework to guide the study. The researchers concurred that utilizing this framework provides a strong theoretical base for educational sessions and allows the opportunity to apply the nurses’ clinical experience. The teaching techniques utilized by the researchers included lecture, discussion, problem-solving simulation, and clinical laboratory demonstration. Educational needs of the nurses were determined using the Educational Needs Assessment Tool. This tool was completed by 44 Directors of Nursing Education. From this information, three courses were designed and implemented, based on the knowledge deficits indicated by the assessment tool. Over a 9 month period, an average of two classes were taught each week, totaling 417 hours. A total of 1,175 nurses participated in the educational sessions offered by the researchers. The effectiveness of the educational intervention was evaluated through a pre-test/ post-test design. Two post-tests were administered, one immediately following the education intervention and the second, 3 months following the educational intervention. Only 12% (n=34) of the participants returned the second post-test. Data were analyzed using the mean, standard deviation, and the student $t$-test. For
the basic oncology course there was an increase in the mean score from the pre-test 25.92 to 30.18 for the post-test ($n=153$). For this comparison group $p = 0.05$. Although a small percentage of the 3-month post-tests were returned ($n=26$), the mean ($M=29.35$) indicates a retention of knowledge. Similar findings were identified in the introduction to a chemotherapy course ($n=152$). There was an increase in the mean score from the pre-test to post-test (18.45 to 25.55). For this group the statistical significance is $p = 0.05$. Only eight of the 3-month post-tests were returned; the mean for the scores for this group was 24.75, again reflecting knowledge retention. In order to evaluate the application of this learning, the researchers collected data on changes observed in chemotherapy administration practices. There was no increase in the amount or frequency of chemotherapy given after the educational intervention. However, two hospitals did report an increased number of orders actually administered by registered nurses, and an increase in the use of already existing supplies (Grant et al., 1996). By utilizing the theoretical framework established by Knowles, the researchers were able to contribute to their desired outcome to educate nurses regarding the identified knowledge deficits. This study also indicates that Knowles’ theory of adult education can be an effective tool to educate nurses about clinical care. In addition, these outcomes reflected both a change in knowledge and a change in behavior.

*Responses to Painful Stimuli*

Malnory et al. (2003) examined the effect of preoperative acetaminophen given as analgesia before circumcision on newborn’s behavioral response. A convenience sample of 53 male newborns was included in the study; 26 were in the experimental group and 27 were included in the control group. The neonatal infant pain scale (NIPS) was used to assess pain in the newborn. NIPS scores were recorded at predetermined intervals: (a) 5 minutes prior to the procedure; (b) during restraint application; (c) at 1 minute intervals intraoperatively; and (d) at 5, 15, 30, and 60 minutes postoperatively. Due to the small sample size and lack of randomization, only descriptive statistics were utilized. Frequency distributions and measures of central tendency were used to analyze the data. The overall mean NIPS scores were lower for infants that received preoperative analgesia. The mean NIPS scores for (a) arm movements for infants that received preoperative anesthesia was 0.27 compared to 0.52 for infants without preoperative
analgesia; (b) leg movements was 0.27 compared to 0.59; (c) state of arousal 0.15 compared to 0.46; (d) facial expressions was 0.24 compared to 0.27; and (d) breathing quality was 0.20 versus 0.38. However, the mean NIPS score for cry was higher for infants that had received preoperative anesthesia, 0.42 compared to 0.33. The authors concluded that nurses should utilize nonpharmacologic interventions, in addition to pharmacologic interventions, to offer effective pain relief during and after circumcision. In addition, the authors utilized the NIPS pain assessment tool and demonstrated its reliability and validity to document infant responses to pain and pain relief interventions (Malnory et al., 2003).

Macke (2001) conducted a study to evaluate the effects of analgesia for circumcision on newborn behavior and mother/infant interaction. A randomized, double-blind, placebo controlled, pretest/posttest design was used. Sixty full-term infants were included in the study. Twenty-nine infants were randomly placed in the acetaminophen group and 31 were placed in the placebo group. Descriptive statistics were used to examine the characteristics of the two groups. In addition, Chi square tests and t-tests were used. Mother infant feeding interactions were measured by the Nursing Child Assessment Feeding Scale (NCFAS) developed by Barnard in 1986. The acetaminophen group was administered 10 mg/kg acetaminophen 1 hour prior to the circumcision, and the placebo group was given the placebo. Pain distress (heart rate and crying) was observed for 10 minutes during a diaper change, and for 10 minutes during a diaper change 1 hour after the circumcision. A feeding was initiated 20 minutes after the circumcision restraint. An analysis of covariance (ANCOVA) was used to test the means of the two groups on the NCFAS, and repeated ANCOVA was used to test heart rates and percentage of cry. The mean score for the NCFAS decreased for the infant experimental group (n = 29) from 61.8 to 59.9. However, the mean score for the infant control group (n = 31) also decreased from 60.0 to 53.5. The ANCOVA for these groups was $F_c = 8.27$ and $p = .01$. The researcher of this study supported the use of nonpharmacologic interventions to reduce pain. The infants that were bundled after the circumcision became either quiet, drowsy, or went to sleep. The researcher cautioned that the nurse must still reassess pain and provide pain relieving measures as needed (Macke, 2001).
In 2002, Harrison et al. evaluated a method of pain assessment to be used for hospitalized infants requiring blood tests by a heel lance procedure. The study included 20 infants in a level III neonatal intensive care and a cardiac surgical unit. This observational study evaluated pain measurement and interrater reliability of pain measurement in hospitalized infants. Observations included behavioral measurements such as facial expressions, body movements, and crying characteristics. The physiologic measure observed was heart rate. The mean percentage of crying was 76% ($SD = 40\%$) during the procedure and 31% ($SD = 40\%$) for the three minutes after the procedure. In addition, all infants had an increase in heart rate in response to the heel lance. Lin’s concordance correlation coefficient was calculated to assess the interrater reliability. The concordance correlation coefficient estimated on the four facial expressions scored during the heel lance procedure was 0.95, with a 95% confidence interval of 0.90 to 0.99. For the three minutes following the heel lance it was 0.98, with a confidence interval of 0.97 to 0.99. This study supports the conclusion that infants experience behavioral and physiologic changes in response to painful stimuli (Harrison et al., 2002).

**Documentation of Pain Assessment and Nonpharmacologic Interventions**

Reyes (2003) conducted an exploratory descriptive study to compare nursing beliefs and practices in assessing infant pain using a prospective questionnaire and a retrospective chart review. The setting was a level III neonatal intensive care unit (NICU) in a regional medical center in a large metropolitan area. The potential sample population for the questionnaire was the 51 registered nurses working in the NICU. The total number of nurses that responded to the questionnaire was 24 (47% response rate). The sample population for the chart review included the 107 admissions for a seven-month time period. Pain assessment data were collected from each chart for the first 24 hours of admission in the NICU. The Intensive Care Pain Questionnaire (ICPQ) utilized a Likert scale for questions relating to the beliefs and practices of the NICU nurses regarding pain assessment. The questionnaires were anonymous and were not linked to the documentation in the chart review. The Pain Assessment and Management Chart Audit Form was created to collect data from the newborn charts. The data collected from the chart included: (a) demographic data; (b) documentation of pain assessments; (c) pain medication administration; (d) documentation of nonpharmacologic interventions;
(e) documentation of pain interventions effectiveness; and (f) pain scores. Pain assessment data were obtained for the following painful procedures: arterial puncture, venipuncture, heel lance, peripherally inserted central catheter insertion, chest tube insertion, and mechanical ventilation. The data were collected from the nurses’ flow sheets, medical administration record, physician orders, and progress notes. The answers on the questionnaires and actual documentation in the newborn record reflected some discrepancies. Of the nurses who returned their questionnaire, 87.5% agreed that documentation of pain leads to more effective pain relief. However, 83.3% of the nurses disagreed that nurses routinely document their pain assessments. Furthermore, 75% of the nurses reported documenting pain assessment at least every 4 hours. However, the chart review found that 62% of the infant charts on day shift and 56.2% of the infant charts on night shift did not have a documented pain assessment. The study found that 289 painful procedures were documented in the newborns’ charts. Of these only 1% (3/289) had a documented follow-up pain assessment (Reyes, 2003).

Alexander and Manno conducted a study in 2003, to compare the use of analgesic agents in very young children with that in older children with isolated painful injuries. A retrospective chart review was conducted of patients seen between 1999 and 2000 in a pediatric emergency center. Patients aged 6 months to 10 years that had sustained isolated long bone fractures or second and third degree burns were included. One hundred and eighty cases met the inclusion criteria. Ninety-six patients were included in the very young group (ages 6 to 24 months) and 84 in the school age group (ages 6 to 10 years). The findings showed that children younger than 2 years received disproportionately less analgesia than school age children for painful injuries. The very young group received no analgesia more often than the school age group for all injuries (64.6% versus 47.6%, respectively). Additionally, only 16.7% of the very young group was administered narcotics, which is considerably less than the 44% of the school age group that received narcotics. The very young group was given over-the-counter medications more often than the school age group (18% versus 7%, respectively). This demonstrates how pain management for the very young child remains inadequate (Alexander & Manno, 2003).
Malek and Olivieri (1996) conducted a descriptive study. Data were collected to examine the pain documentation practices of the staff nurses through formal chart reviews. A convenience sample of patients who had undergone orthopedic surgical procedures was used. A 25-item Nurses’ Pain Management Audit Tool (NPMAT) developed by the authors served as the data collection tool. The tool was piloted on five patient’s charts, and there was a 93% agreement of the tool. The NPMAT captured information about both the documentation of pharmacologic and nonpharmacologic interventions. All of the patients had a documented nursing diagnosis of pain in the nursing care plan. However, there was a documentation rate of 19.7% of the “ideal occurrences” relating to pain assessment. An “ideal occurrence”, was defined by the author as one entry related to pain every 2 hours for a 24-hour period after emergence from the Post Anesthesia Care Unit. The authors theorized that a minimum of one nonpharmacologic intervention should be documented in the nurses’ notes every 8 hours. Unfortunately, there were no documented entries of cognitive-behavioral interventions in the 23 reviewed charts. However, there were 17 entries relating to exercise intervention, which represents 24% of the “ideal occurrences.” The chart review revealed that, on average, the patients were administered 49% of the possible doses of narcotics that each patient was prescribed for the 24-hour post-operative period. The average was 3.9 doses per patient. This study illustrates that pain assessment documentation was inadequate (Malek & Olivieri, 1996).

Educational Interventions

Rond, Wit, Dam & Muller (2000) conducted a study in three Dutch hospitals. The purpose of the study was to develop, implement, and evaluate a Pain Monitoring Program (PMP) for nurses. This program focused on educating nurses about pain, pain assessment, and pain management. The program also focused on implementing daily pain rating by means of a numeric scale. The study was conducted using a quasi-experimental design with a nonequivalent control group. In total, 703 patients participated. There were 358 in the control group and 345 in the intervention group. Nurses in the control group documented pain intensity in the medical records a mean of 3.4 times ($SD = 4.5$) per patient. The PMP was effective in improving assessment of pain and documentation in medical records. After implementation of the PMP, the mean
number of pain intensity scores in the medical record increased to 5.1 ($SD = 6.8$) per patient (Rond et al., 2000).

Derebery, Giang, Saracino, and Fogarty (2002) designed a study to evaluate the impact of a low back pain educational intervention on physicians’ practice patterns and patient outcomes. This study employed a change strategy to meet the desired objectives that was modeled after a business strategy to overcome resistance to change. This strategy consisted of three steps: (a) Provide disconfirmation; (b) Emphasize that change is necessary; and (c) Provide specifics on how to accomplish change. Therefore, the educational intervention was designed to increase awareness of the problem, to give the physicians a sense of responsibility for the problem, and to provide specific methods to address the problem. A total of 107 physicians participated in the educational intervention; of this number, 64 were included in the study, based on the established inclusion criteria. Cases were reviewed and compared prior to the educational intervention and after the intervention. A total of 4411 cases were reviewed prior and 4465 cases after the intervention. The study showed that the percentage of patients placed on restricted duty decreased dramatically from 82.89% to 66.38% in the study group after the education intervention. In addition, the duration of restricted duty decreased significantly after the education intervention from 11.04 to 9.92 days. After the intervention, there was also a marked decrease in the patients removed from duty from 4.85% to 2.77%. The number of physical therapy and physician visits decreased from 4.53 to 4.21 and 3.11 to 2.93, respectively. The educational intervention effectively reduced the case duration from 13.70 to 12.37 days (Derebery et al., 2002). This study demonstrates how an educational intervention can effectively change practice patterns related to pain management.

Francke, Luiken, Schepper, Abu-Saad, and Grypdonck (1997) conducted a study on the effects of a continuing education program on the nurses’ pain assessment practices. The effectiveness of an education program was tested using a pretest/posttest design. The study took place in five Dutch hospitals and included 106 surgical nurses. Nurses were randomly placed in either the control or the experimental group. An education intervention was conducted in 8 weekly sessions of 3 hours each. Verbal and audiovisual presentations, discussions, practical exercises, and research literature were
utilized by the researchers. Nurses in both groups were asked to fill out a questionnaire about pain at three intervals: (a) prior to the intervention; (b) 1 month after the intervention; and (c) at 6 months after the intervention. An 18-item Pain Assessment Questionnaire was used to measure the number and quality of activities regarding pain history taking by the nurse. Eight pain experts established the content validity of the Pain Assessment Questionnaire and it was piloted on a group of 15 nurses. The internal consistency was evaluated using Cronbach’s correlation coefficient (0.93). The continuing education program did not significantly affect the number and quality of nurses’ pain intensity assessments. There was no significant difference in trends over time ($f_{c} = 2.19$, $df = 2,103$, $p = 0.09$). However, there was an increase in the experimental nurses’ quality of activities relevant to taking pain histories ($f_{c} = 21.53$, $df = 2,103$, $p < 0.001$). This increase was most apparent shortly after the program (T2), but was still observable in time period three (Francke et al., 1997).

Salantera et al. (1999) conducted a study in Finland to examine nurses’ knowledge about pharmacologic and nonpharmacologic pain management in children. A convenience sample of 265 nurses working on children’s units in university hospitals was given a questionnaire. The questionnaire consisted of demographic questions and questions regarding both pharmacologic and nonpharmacologic pain intervention. The mean number of questions answered correctly about nonpharmacologic pain intervention by the nurses was 63% (16.9) and the median was 67%. The mean number of questions answered correctly for pharmacologic pain intervention was 51% (17.4) and the median was 52%. The nurses surveyed reported using a mean of 9.4 (3.4) nonpharmacologic methods out of 20 methods with children experiencing pain. The study showed that there was a knowledge deficit by nurses for pharmacologic and nonpharmacologic methods to alleviate pain. The researchers concluded that there is a clear need for further education for nurses about pain management utilizing nonpharmacologic interventions for children (Salantera et al., 1999).

In a study conducted by Halimaa et al. (2001), a semi-structured questionnaire was sent to 280 registered nurses, practical nurses, and laboratory technologists that routinely drew labs on infants. A total of 197 caregivers completed the questionnaire. The study found that 41% of the health care professionals surveyed felt that not enough
attention was paid to premature infants’ pain. In addition, 39% of the respondents felt that the pain of premature infants was treated inadequately. The need for more education about pain management in newborns was reflected in this study. More than 90% of the health care professionals surveyed stated that they needed more knowledge about premature babies’ pain and its identification. The study also found that 86-95% of the caregivers wanted more information about pain alleviation. The study also demonstrates the knowledge deficits associated with newborn pain. The study found that 7% of health care professionals surveyed felt that premature babies do not sense pain as easily as full term infants (Halimaa et al., 2001).

**Summary**

Through the review of the literature it was illustrated that utilizing Dorothea Orem’s Self Care Deficit Theory (2001) and Malcolm Knowles’ principles of andragogy (1998) provides an appropriate framework for this study. The self-care deficit theory can assist the nurse in identifying self-care deficits of the newborn and guide the nurse in implementing nonpharmacologic interventions to minimize the difference between the infant’s self-care agency and self-care demands (Dennis & Jesek-Hale, 2003; Tolentino, 1990). Lenatsch (1999) conducted a study that supported the use of Dorothea Orem’s Self Care Theory as an effective framework in identifying knowledge deficits and promoting a supportive-educative system to assist patients in meeting self-care demands. The principles of andragogy (Knowles, 1998) can be utilized to guide educational interventions for adult learners. Grant et al. (1996) conducted a study to evaluate the effectiveness of a community-based educational program for cancer nursing and supported utilizing the principles of andragogy for educational sessions by allowing the opportunity to apply the nurses’ clinical experience.

The physiology of newborn pain is basically the same as it is for adults. Infants are capable of nociception and can perceive pain at birth (Michell & Boss, 2003; Walden & Francke, 2003). Pain is a normal physiologic response. However, prolonged or frequent pain can have many negative effects on the newborn. Painful stimuli can have short term and long term adverse effects on the nervous system of the newborn (Mitchell & Boss, 2003). Infants undergoing painful procedures experience physiologic, behavioral, biochemical, hormonal, and metabolic changes (Halimaa et al., 2001;
Harrison et al., 2002). The newborn has the right to accurate pain assessment and pain management to avoid needless suffering and potential short and long term consequences of untreated pain. There are several routinely performed painful procedures on the newborn including circumcision, heel lance, venipuncture and lumbar puncture (Gallo, 2003). Infants that undergo painful procedures are entitled to the same level of pain assessment and relief as the adult patient.

Despite evidence that infants experience pain, and the development of tools to assess pain, infant pain management documentation remains inadequate (Alexander & Manno, 2003; Bildner & Krechel, 1996; Bookbinder et al., 2002; Gallo, 2003; Halimaa, 2001; Harrison, 2002; Reyes, 2003; Rutledge & Donaldson, 1998). To manage pain adequately, pain assessments should be conducted every times vital signs are taken and after painful procedures (JCAHO, 2001). Without documentation in the medical record of pain assessment and nonpharmacologic interventions it is impossible to evaluate the effectiveness of pain management for newborns (AHCPR, 1992; Halimaa, 2003). It is the moral and ethical obligation of nurses to provide adequate pain assessment, intervention, and follow-up (Curtiss, 2001).

Nonpharmacologic interventions can be useful in decreasing pain in infants (AHCPR, 1992). Many researchers recommend multimodal approaches to neonatal pain management, which include nonpharmacologic interventions (Geyer et al., 2002; Kraft, 2003; Macke, 2002; Malnory et al., 2003). Salantera et al. (1999) found that nurses have knowledge deficits related to pharmacologic and nonpharmacologic interventions in children. Furthermore, nonpharmacologic interventions to alleviate pain are rarely documented in the medical record (Gallo, 2003; Reyes, 2003).

Pain assessment is subjective and can be influenced by nursing knowledge deficits associated with pain (Bildner & Krechel, 1996; Gallo, 2003; Rond et al., 2000). Research indicates that staff education regarding pain pathophysiology, assessment, and management is a key element in the successful implementation of an effective pain assessment program (American Academy of Pediatrics, 2000; Collins, 1999; Halimaa et al., 2001; Howard & Thurber, 1998; Rutledge & Donaldson, 1998). Staff education is recommended in improving pain management (American Academy of Pediatrics, 2000; Derebery et al., 2002; Francke et al., 1997). The advanced practice nurse can guide the
education of nurses in increasing the documentation of pain assessment and nonpharmacologic interventions (White, 1999). The methodology and study design are discussed in Chapter 3.
CHAPTER 3
METHODOLOGY

This chapter outlines the research methodology, setting, population and sampling plan, instruments, procedure, protection of human subjects, and analytical procedures used for this study. These discussions were guided by the study objectives and research questions specified in Chapter 1 and repeated herein.

Design

The purpose of this inquiry was to evaluate the effectiveness of a comprehensive intervention for increasing the assessment documentation of newborn pain as well as the frequency and documentation of nonpharmacologic newborn pain management. The quasi-experimental study utilized a repeated measures design and retrospective as well as cross-sectional data to investigate the effectiveness of the intervention for increasing the assessment documentation of newborn pain. Patient charts, meeting the required inclusion criteria, were sampled and base-line data extracted from a period of time immediately prior to the implementation of the policy change and educational intervention. Another sampling was accomplished approximately 3 months post-program implementation. The final sampling and test of the program’s effectiveness occurred approximately 1 year subsequent to the program’s implementation. The number of documented pain assessments and nonpharmacologic interventions were collected via a pain flow sheet that was created by the researcher. The methodology was quasi-experimental because although a treatment effect was being sought as evidence of program effectiveness, there was no randomization of subjects to treatment and control groups.
Setting

The setting for this research was a Level I nursery in a not-for profit, private corporation. This large institution includes 770 licensed beds (597-bed tertiary hospital, a 60 bed psychiatric hospital, and a 53-bed sub-acute facility.) This institution is a teaching hospital with a family practice residency program, which consists of 11 faculty and 30 residents. The medical staff includes 435 physicians. This regional medical center serves of a population base of about 600,000 in 16 counties in north Florida, southwest Georgia, and southeast Alabama. The hospital derives 80.8% of its admissions from its primary service area. The metropolitan area that comprises this primary service area has a population of 322,000, and is ranked as the most heavily concentrated managed care area in the state. In contrast, the primary service area also includes rural counties which have a low per capita income and have government insurance programs. This facility is the 10th leading Medicaid provider in the state of Florida. The maternal-child services area delivers approximately 3,000 infants per year.

Population/ Sampling Plan

The target population was the infinite number of charts of newborns that met the inclusionary criteria during the three time periods: Time Zero (May, 2003), Time One (September, 2003), and Time Two (September, 2004). The sampling frame (accessible population) was the charts of newborns that were discharged from the Level I nursery in the selected setting during the three time periods specified. The criteria for inclusion in the sample were infants admitted and discharged from the Level I nursery, which admits newborns with a gestational age of 35 weeks and greater. Infants that were transferred to the Level II or Level III nursery at anytime during their hospitalization were not included in the study.

The sampling frame (accessible population) for phase two of the programmatic intervention was those nurses working in the Family Care Unit who attended to the newborn patients in the Level I nursery meeting the inclusion criteria during the time frames for which the charts were sampled. The family care unit in the not-for profit regional medical center located in North Florida previously described employs approximately 65 nurses and has a capacity for 38 mother/baby couplets.
**Sampling Plan**

Newborn charts for patients meeting the inclusion criteria were randomly selected from three time periods: immediately prior to the implementation of the education program, approximately 3 months post implementation, and finally, approximately 1 year post implementation. For each of the three time periods 80 charts were randomly selected from the approximate 300 discharges from the Level I nursery for the one month period specified (May, 2003; September, 2003; and September, 2004). Random selection was achieved using a Microsoft Excel application. The Microsoft Excel tool used to select the sample was a random selection process that required input of the size of the population, and a specification of the sample in terms of type. The population selected in Microsoft Excel for this study was uniform so that every score in the distribution had an equal opportunity of being selected. While an attempt was made to keep the sample sizes equal for all three sampling periods, such was not possible due to census irregularities. A minimally adequate sample size was determined \(n = 73\) charts) from the sample size tables of Cohen (1988) and consideration of: alpha \(\alpha = .10\), Power \([1-\beta] = .80\) and Effect size \(ES = 20\%\). The effect size was determined based on evidence found in the research literature. Gallo (2003), found an increase in pain assessment documentation by nurses of 27% after an initial educational intervention.

**Protection of Human Subjects**

Prior to implementation, the study was reviewed and approved by the Institutional Review Board at Florida State University (Appendix A) and at the selected hospital (Appendix B). Each participant was provided information about the study, and signed a written consent form (Appendix C). Participation was voluntary, and participants could withdraw from the study at any point without penalty. Confidentiality was maintained, to the extent allowed by law, throughout the study. The Demographic Questionnaire (Appendix D) was completed by the nurses for the purpose of describing characteristics of nurses caring for newborn patients, and no identifying information was collected that links the nurse to the charts and corresponding data. Names were not collected from the nurses or from the medical records. Nor was any identifying information of the newborn patients collected from the medical record. Identification numbers were assigned to data sheets. Data were kept in a locked file cabinet in the researcher’s office at the hospital,
and only the researcher and research committee have access to the data. All data will be destroyed in May, 2010. Findings are reported using group data. There was minimal risk related to participating in the study. The risks involved were minimized and were reasonable in relation to the anticipated benefits of the research. There was a risk that participants may have experienced emotional stress related to anxiety or guilt when reflecting on past pain management practices. Therefore, participants were provided with the researcher’s and clinical nurse specialists contact information to discuss any emotional discomfort experienced.

**Instruments**

Data for this study were collected through a thorough chart review. The pain assessment and nonpharmacologic intervention Chart Audit Tool, created by the researcher, was used for this purpose (Appendix E). The data collected were simply a summary of the information located within the chart. The tool was used to facilitate data collection. Therefore, validity and reliability tests were not applicable to this tool. Pain assessment documentation and nonpharmacologic intervention documentation were evaluated using a frequency count. To gain further insight into the sample, a Demographic Questionnaire was administered to the nurses that participated in the educational intervention.

Pain assessment was measured using the Neonatal Infant Pain Scale (NIPS). NIPS assesses six behavioral indicators in response to painful procedures. The six behavioral indicators include: (a) facial expression; (b) cry; (c) breathing patterns; and (d) state of arousal; and (e) motor activity (arm and leg movement). A score of 3 or higher is indicative of pain and requires documentation of interventions and reassessment in 15 minutes. The scale has been demonstrated to be valid and reliable. The NIPS has demonstrated high interrater reliability with Pearson correlations ranging from .92 to .97. Internal consistency has been shown with Cronbach’s alphas ranging from .53 to .84. Construct validity has also been demonstrated with Pearson correlations ranging from .53 to .84 (Lawrence, Alcock, McGrath, Kay, MacMurray & Delberg, 1993).

**Procedure**

This study evaluated the effectiveness of a programmatic intervention for increasing the documentation of newborn pain assessment, using the Neonatal Infant Pain Scale.
Scale (Appendix F) as well as the frequency and documentation of nonpharmacologic newborn pain management following circumcision, heel lance, venipuncture, and lumbar puncture procedures. To accomplish this objective, a quasi-experimental methodology was utilized with a repeated measures design using retrospective and cross-sectional data.

**Time Zero**

Patient charts meeting the required inclusionary criteria were randomly sampled and the data collected represented a base-line of pain assessment documentation prior to the onset of the two phases of the programmatic intervention.

**Time One**

A random sample of charts were selected 3 months following phase one of the intervention. Phase one of the intervention consisted of an institutional policy change including redesigning and implementing a revised nurses’ flow sheet, which included a column to document a NIPS score, education about the NIPS, implementing a new pain management policy and algorithm, and a poster presentation that provided education about the NIPS tool.

**Time Two**

The researcher provided phase two of the programmatic intervention, which consisted of a follow-up educational intervention on utilization and documentation of pain assessment after painful procedures and nonpharmacologic interventions. The educational intervention followed the objectives and format established by Gallo (2003), which is in public domain (Appendix G). The education reinforced previous learning and included the physiology of pain and documentation of pain assessment. In addition, the researcher focused on documentation of pain assessment following painful procedures and nonpharmacologic interventions. The material was provided in a 30-minute presentation which was presented three times each day for a 1-week period. At the conclusion of the presentation, there was a 15 minute question and answer session. Each nurse on the family care unit received an invitation to the educational session (Appendix H). Informed consent was obtained by the researcher when participants arrived for the educational session. Participants were given a brief description of the study and were asked to sign the informed consent which allowed the researcher to evaluate characteristics of nurses caring for newborn patients. Participants that did not wish to
participate could leave at that time, without penalty. Participants that did not wish to participate were allowed to stay for the educational interventions if they chose.

Approximately 30 days after this educational intervention a final random selection of charts was reviewed. This final chart review and test of the program’s effectiveness occurred approximately 1 year subsequent to the program’s implementation. The trends in documentation were used to evaluate the effectiveness on the entire programmatic intervention. The change in documentation between Time Zero and Time One was used to evaluate the effectiveness of a policy change and implementation of the NIPS on documentation of pain assessment. The change in documentation between Time Zero and Time Two was used to evaluate the effectiveness of the programmatic intervention in its entirety.

**Data Analysis**

Both descriptive and inferential statistical techniques were utilized to address the following research questions. A minimally adequate sample size was determined for the inferential procedures, related-Samples \( t \)-test and/or one or more analogous nonparametric procedures, with the larger of the requirements being used for both. The minimally adequate sample size was 73 charts for each of the specified time periods.

*Research Question One*

Research Question one inquired of the effect of the programmatic intervention on the assessment documentation of newborn pain following circumcision, heel lance, and lumbar puncture procedures. The “effect” of the program was determined by comparison of the difference in proportions of documentations by attending nurses before and after the intervention and then subjected to analysis with the two-related samples \( t \)-test.

The two-related samples \( t \)-test was chosen because the researcher cannot argue for independence of documentation behaviors before and after the intervention since some of the nurses were included in the repeated samplings of charts. The other assumptions required for this test were: (a) that the population of difference-scores were normally distributed, (b) the observations (difference scores) were independent, and (c) that the sample of charts was randomly selected. The researcher chose to report a non-parametric procedure in addition to the \( t \)-test data since the samples of scores were not perfectly symmetric. There was no way to verify or test the independence assumption.
With respect to the requirement of random-selection, such was completed with the use of the random selection function in Microsoft Excel, as previously described.

The null hypothesis was that the intervention would have no effect on the proportion of assessment documentations. The alternate hypothesis was directional and specified that the intervention would have a positive effect on the proportion of assessment documentations.

**Research Question Two**

The second research question was concerned with the effect of the intervention on the frequency and documentation of nonpharmacologic management of newborn pain. This question was answered in a manner consistent with research question one. Likewise, the null and alternate hypotheses were identical with the exception of the dependent variable of interest.

**Research Question Three and Four**

Research questions three and four were descriptive in nature and inquired of the nurse characteristics which were found to be associated with the assessment documentation and nonpharmacologic management behaviors, respectively. These questions were answered after detailed demographic and work-related descriptions of the attending nurses were collected. The data were then scrutinized for trends and correlation coefficients were generated for all relevant variables reported in tables and charts.

**Summary**

This chapter described the research methodology that provided the framework for this study. The setting and sample were also described, which includes the protection of the human rights of the participants. Analyses and study findings are presented in Chapter 4.
CHAPTER 4
RESULTS

This quasi-experimental study utilized a repeated measures design and retrospective as well as cross-sectional data to investigate the effectiveness of a programmatic intervention for increasing the assessment documentation of newborn pain. Also of interest was the effect of the intervention on the frequency and documentation of nonpharmacologic newborn pain management. The purpose of the chapter is to present and discuss the results of the study. The discussion of the findings and presentations are given with respect to each of the research questions to facilitate the reader’s understanding.

Description of the Sample

To evaluate the documentation of pain assessment and nonpharmacologic interventions by the nurses, chart reviews were conducted and compared over three time periods. The Level I nursery in this regional medical center in north Florida admits newborns with a gestational age of 35 weeks and older. Painful procedures are necessary to provide the level of care appropriate for these infants. A sample of 54 nurses (83%), from an accessible population of 65 nurses employed by the family care unit in a not-for-profit regional medical center in north Florida, participated in phase two of a programmatic intervention consisting of an education intervention provided by the researcher.

Eighty charts of patients meeting the criteria for inclusion were randomly selected from the accessible population (approximately 300) of all such patients for each of the three time periods. Of the 80 charts selected for each time period, charts of patients that did not meet the inclusion criteria were not included in the sample, resulting in a small variation between sample sizes for the three time periods. A total of 240 medical records were reviewed, 211 of these met the inclusionary criteria and were included in the study.
**Time Zero**

For Time Zero (May 2003), 69 patient charts of the randomly selected sample met the criteria for inclusion. The accessible population was 344 newborns discharged from the Level I nursery during this 1-month time period. The data obtained from this sampling represented a baseline of pain assessment documentation prior to the onset of the two phases of the intervention. Characteristics of the nurses could not be obtained for this time period due to the fact that this was retrospective data and such personnel data could not be made available to the investigator.

**Time One**

For Time One (September, 2003), 70 charts of the randomly selected sample met the criteria for inclusion for this time period which was 3 months following phase one of the intervention: an institutional policy change. The accessible population for this time period was 363 charts of newborns discharged from the Level I nursery during the one-month time period. The policy change consisted of redesigning and implementing a revised nurses’ flow sheet, which included a column to document a NIPS score, education about the NIPS, and a poster presentation. Again, due to the circumstances described in Time Zero, nurse characteristics were not available for this time period.

**Time Two**

For Time Two (September 2004), 72 charts of the randomly selected sample met the criteria for inclusion which followed phase two of the intervention, a detailed educational in-service which provided a follow-up educational intervention on utilization and documentation of pain assessment after painful procedures and nonpharmacologic interventions. The accessible population for Time Two was 295 charts. The educational intervention followed the objectives and format established by Gallo (2003), which is in public domain (Appendix E). The education reinforced previous learning and included the physiology of pain and documentation of pain assessment. In addition to patient data, demographic information was obtained from a nonrandom sample \( n = 54 \) of nurses who participated in the phase two of the intervention. Upon scrutiny of the nurse data, it was discovered that 53.7\% (29/54) of these nurses were, in fact, employed by the host facility during both phases of the intervention.
**Documentation of Pain Assessment**

**Research Question One**

Research Question One inquired of the effect of the programmatic intervention on the assessment documentation of newborn pain following circumcision, heel lance, venipuncture, and lumbar puncture procedures. The tool used to obtain these data was the Chart Audit Tool created by the researcher. This question was addressed both descriptively and inferentially. Table 1 illustrates the frequency of painful procedures for each of the three chart samples and time periods of the study.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>Time Zero n=69</th>
<th>Time One n=70</th>
<th>Time Two n=72</th>
<th>Total N=211</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heel Lance</td>
<td>69</td>
<td>68</td>
<td>71</td>
<td>208</td>
</tr>
<tr>
<td>Circumcision</td>
<td>24</td>
<td>23</td>
<td>14</td>
<td>61</td>
</tr>
<tr>
<td>Venipuncture</td>
<td>8</td>
<td>14</td>
<td>13</td>
<td>35</td>
</tr>
<tr>
<td>Other Procedure</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Zero Procedures</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>One Procedure</td>
<td>31</td>
<td>35</td>
<td>42</td>
<td>108</td>
</tr>
<tr>
<td>Two Procedures</td>
<td>30</td>
<td>18</td>
<td>19</td>
<td>67</td>
</tr>
<tr>
<td>Three Procedures</td>
<td>5</td>
<td>7</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Four Procedures</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Five Procedures</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Six Procedures</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Seven Procedures</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Eleven Procedures</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total Procedures</td>
<td>119</td>
<td>139</td>
<td>115</td>
<td>388</td>
</tr>
</tbody>
</table>

**Time Zero.** For Time Zero (n = 69), 75.4% (52/69) of the charts did not have any NIPS scores documented in the medical record, 15 (21.7%) contained one NIPS score and two (2.9%) of the charts had two NIPS scores recorded. All 69 patients underwent at least one painful procedure, and 38 (55%) underwent at least two, indicating that less than 25% of the patients’ charts contained documentation of pain assessments. There was only one chart that indicated an assessment for pain within 1-2 hours after a painful procedure and the proportion of total NIPS to total procedures was 14.2 %. A total of 119 painful procedures were documented in the nurses’ notes.

**Time One.** For Time One (n = 70), 100% of the medical records had pain assessment documented in the nurses’ notes, using the NIPS. As can be seen in Table 2,
the minimum number of NIPS scores documented for this time period was 5 and the maximum was 15. The mean number of NIPS scores documented was 8.11 (median = 8.00, SD = 1.68).

Table 2

*Time One: Frequencies and Percentages for NIPS Assessment Scores*

<table>
<thead>
<tr>
<th>Total # of NIPS Assessment Scores in Chart</th>
<th>f</th>
<th>%</th>
<th>Cumulative %</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>3</td>
<td>4.3</td>
<td>4.3</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>7.1</td>
<td>11.4</td>
</tr>
<tr>
<td>7</td>
<td>16</td>
<td>22.9</td>
<td>34.3</td>
</tr>
<tr>
<td>8</td>
<td>24</td>
<td>34.3</td>
<td>68.6</td>
</tr>
<tr>
<td>9</td>
<td>12</td>
<td>17.1</td>
<td>85.7</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>7.1</td>
<td>92.9</td>
</tr>
<tr>
<td>11</td>
<td>3</td>
<td>4.3</td>
<td>97.1</td>
</tr>
<tr>
<td>13</td>
<td>1</td>
<td>1.4</td>
<td>98.6</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
<td>1.4</td>
<td>100.0</td>
</tr>
<tr>
<td>Total Charts</td>
<td>70</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>Total Documented Assessments</td>
<td>568</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In this data set, there were a total of 139 painful procedures documented in the nurses’ notes, 13.7% (19/139) of these procedures had a pain assessment documented 1-2 hours following the procedure. Likewise all 70 charts reviewed, 18.6% (13/70) of the charts had at least one pain assessment documented post-procedure. Table 3 illustrates the frequency and percentages of painful procedures documented post-procedure.

Table 3

*Time One: Frequencies and Percentages for NIPS Assessment Scores Post-Procedure(s)*

<table>
<thead>
<tr>
<th>Total # of NIPS Assessment Scores Post-Procedure(s)</th>
<th>f</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>56</td>
<td>81.2</td>
</tr>
<tr>
<td>1</td>
<td>9</td>
<td>13.0</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2.9</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>2.9</td>
</tr>
<tr>
<td>Total Charts</td>
<td>69</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Documented Assessments Post-Procedure(s) 19

44
**Time Two.** The second phase of the programmatic intervention consisted of an educational in-service provided by the researcher that focused on documentation of pain assessment and nonpharmacologic interventions following painful procedures. While the mean number of NIPS scores documented for Time Two was slightly less (mean = 7, median = 7.00, $SD = 2.25$) than for Time One, 100% of the sampled charts had at least one NIPS score documented. The range of NIPS scores for this period was similar to Time One, with a minimum of 2 and a maximum of 14. Since, the second phase of the educational intervention focused on documentation of pain assessment following painful procedures, an increase for this variable from Time One to Time Two was expected. The total number of painful procedures performed was 115; of these 25 had a documented pain assessment after the procedure. For Time Two, 29.2% (21/72) of the medical records had a pain assessment documented after a painful procedure. Table 4 illustrates the frequency and percentages of NIPS assessment scores in the selected medical records. Likewise, Table 5 presents the frequency and percentages of pain assessment scores 1-2 hours after painful procedures.

Table 4

**Time Two: Frequencies and Percentages for NIPS Assessment Scores**

<table>
<thead>
<tr>
<th>Total # of NIPS Assessment Scores in Chart</th>
<th>$f$</th>
<th>%</th>
<th>Cumulative %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>5.6</td>
<td>6.9</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>5.6</td>
<td>12.5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>8.3</td>
<td>20.8</td>
</tr>
<tr>
<td>6</td>
<td>13</td>
<td>18.1</td>
<td>38.9</td>
</tr>
<tr>
<td>7</td>
<td>18</td>
<td>25.0</td>
<td>63.9</td>
</tr>
<tr>
<td>8</td>
<td>13</td>
<td>18.1</td>
<td>81.9</td>
</tr>
<tr>
<td>9</td>
<td>4</td>
<td>5.6</td>
<td>87.5</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>6.9</td>
<td>94.4</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>1.4</td>
<td>95.8</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>1.4</td>
<td>97.2</td>
</tr>
<tr>
<td>13</td>
<td>1</td>
<td>1.4</td>
<td>98.6</td>
</tr>
<tr>
<td>14</td>
<td>1</td>
<td>1.4</td>
<td>100.0</td>
</tr>
<tr>
<td>Total Charts</td>
<td>72</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>Total Documented Assessments</td>
<td>504</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 5

*Time Two: Frequencies and Percentages for NIPS Assessment Scores Post-Procedure(s)*

<table>
<thead>
<tr>
<th>Total # of NIPS Assessment Scores Post-Procedure(s)</th>
<th>( f )</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>51</td>
<td>70.8</td>
</tr>
<tr>
<td>1</td>
<td>17</td>
<td>23.6</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>5.6</td>
</tr>
<tr>
<td>Total Charts</td>
<td>72</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Documented Assessments Post-Procedures

<table>
<thead>
<tr>
<th>Documented Assessments Post-Procedures</th>
<th>( f )</th>
<th>( % )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented Assessments Post-Procedures</td>
<td>25</td>
<td>29.2% of charts; 21.7% of Procedures</td>
</tr>
</tbody>
</table>

Both parametric and nonparametric statistical tests were conducted to test the significance of the changes in the dependent variables (Documentation of Assessments, Documentation of Assessments Post-Procedure, and Documentation of Nonpharmacologic Interventions). The Null Hypothesis for all statistical tests was that the intervention would be ineffective for increasing the documentation behaviors of the nurses. The alternate hypotheses were all directional and posited that the intervention would have a positive effect on the documentation behaviors of the nurses. Before subjecting the data to analysis, the frequencies were transformed to proportions or probabilities to facilitate interpretation of the results with respect to the differences in sample size. The “effect” of the program was determined by comparison of the difference in proportions of documentations by attending nurses before and after the intervention and then subjected to analysis with the two-related samples \( t \)-test (parametric), the Wilcoxon Signed Ranks Test (nonparametric) and the Sign Test (nonparametric). The two nonparametric tests were conducted for the following reasons:

1. Although the central limit theorem can be invoked for the distribution of difference scores in this research context, the samples of these scores were not perfectly symmetrical and thus the reader may be more comfortable with a statistical test which does make the normality assumption.

2. Despite the fact that the frequency scores for each of the dependent variables were transformed to proportions, the reader may have difficulty with the scale of measurement (interval) required for the traditional \( t \)-test and the thus the ordinal
scale minimally required for both of these nonparametric tests may give the reader an added measure of comfort with their resulting $p$ values.

3. Both the Wilcoxon Signed Ranks test and the Sign test will, with accommodating sample sizes, result in an Exact $p$ value unlike the $t$-test which can only result in an approximation of an Exact $p$ value. When the sample size is large enough, such that an Exact $p$ cannot be calculated, SPSS (version 12) will return an “asymptotic” approximation of the exact $p$ value.

4. Finally, both the Wilcoxon and the Sign test were conducted because although both test statistics treat the data in a similar fashion, the Sign test relies solely on positive and negative changes in the data (Time Zero to Time One, Time Zero to Time Two and Time One to Time Two) while the Wilcoxon converts the differences in signs to ranks and then utilizes the means of the ranks in its test statistic. The more similar the results ($p$ values and their relationships to the test criterion) the more comfortable should be the reader with the resulting statistical conclusions.

Table 6 presents the results of the statistical tests for documented assessments after painful procedures across the three time periods.

Table 6

| Results of Statistical Tests of Significance for Pain Assessments Post-Procedures |
|----------------------------------|------------------|------------------|-----------------|-----------------|-----------|
| Proportional Difference in Assessment Documentation After Painful Procedures | Mean | SE | $t_c$ | $df$ | $p$ |
| Paired Samples $t$-test | | | | | | |
| Time 0 to Time 1 | .00378 | .00118 | 3.192 | 67 | .002 |
| Time 0 to Time 2 | .00442 | .00097 | 4.535 | 68 | <.001 |
| Time 1 to Time 2 | .00029 | .00143 | 0.205 | 68 | .838 |
| Wilcoxon Signed Ranks Test | | | $Z_c$ | Asymp $p$ | |
| Time 0 to Time 1 | 2.750 | | .006 |
| Time 0 to Time 2 | 3.620 | | <.001 |
| Time 1 to Time 2 | .600 | | .549 |
| Sign Test | | | $Z_c$ | Exact $p$ | Asymp $p$ | |
| Time 0 to Time 1 | | | .002 | | |
| Time 0 to Time 2 | | | <.001 | | |
| Time 1 to Time 2 | | | .189 | | .850 |
A positive proportional difference represents a difference in the optimal direction (as specified by the alternate hypothesis). There was an increase in the proportional differences in pain assessment post-painful procedures for: Time Zero to Time One; Time Zero to Time Two; and for Time One to Time Two.

These results of this study are of clinical importance. The \textit{a priori} effect size was set as 20\%, based on the research literature. When examining the entire programmatic intervention (Time 0 versus Time 2) the effect size for documented pain assessment following procedures was 33.25\%. These results support the use of a programmatic intervention to increase documentation of pain assessment after painful procedures by the nursing staff.

**Documentation of Nonpharmacologic Interventions**

\textit{Research Question Two}

The second research question was concerned with the effect of the intervention on the frequency and documentation of nonpharmacologic management of newborn pain. To address this question, data were analyzed using descriptive and inferential statistics. The Chart Audit Tool, created by the researcher, was used to collect these data. A total of 211 medical records were reviewed and the data were compared over three periods of time. Table 7 illustrates the variety of nonpharmacologic interventions that were documented in the medical records.

\begin{table}[h]
\centering
\caption{Frequencies: Nonpharmacologic Interventions Documentation}
\begin{tabular}{lcccc}
\hline
                        & Time Zero & Time One & Time Two & Total  \\
                        & \(n = 69\) & \(n = 70\) & \(n = 72\) & \(N = 211\) \\
\hline
Reposition             & 0         & 0         & 1         & 1       \\
Wrap and Swaddle       & 2         & 0         & 10        & 12      \\
Breast/Bottle feed     & 2         & 0         & 5         & 7       \\
Hold                   & 0         & 2         & 5         & 7       \\
Reduce Stimulation     & 0         & 0         & 0         & 0       \\
Rock                   & 0         & 0         & 0         & 0       \\
 Pacifier              & 0         & 0         & 0         & 0       \\
Skin to Skin           & 0         & 0         & 1         & 1       \\
Other                  & 0         & 0         & 7         & 7       \\
\hline
Total Interventions    & 4         & 2         & 29        & 35      \\
\hline
\end{tabular}
\end{table}
In the Time Zero, the first set of newborn charts reviewed \((n = 69)\) displayed four nonpharmacologic interventions documented. For Time One \((n = 70)\), there was a decrease in the frequency of nonpharmacologic interventions documented in the nurses’ notes. For this time period there were only two nonpharmacologic interventions documented. For Time Two \((n = 72)\), there was an increase in the frequency of nonpharmacologic interventions documented in the nurses’ notes, for a total of 29. There was a mean of 0.43 (median=0.00, \(SD = 0.78\)) nonpharmacologic interventions documented.

The null hypothesis was that the intervention would have no effect on the proportion of documentation of nonpharmacologic interventions. The alternate hypothesis was directional and specified that the intervention would have a positive effect on the proportion of nonpharmacologic interventions. The “effect” of the program was determined by comparison of the difference in the proportion of documentations by attending nurses before and after the intervention and then subjected to analysis with the two-related samples \(t\)-test. As indicated, there was an increase in the mean number of nonpharmacologic interventions documented. The documentation of nonpharmacologic interventions were subjected to analysis with the two-related samples \(t\)-test (parametric) and the Wilcoxon Signed Ranks Test (nonparametric) and the Sign Test (nonparametric). The two nonparametric tests were conducted due to the reasons previously mentioned with respect to the analytical assumptions of the \(t\)-test. The analytical assumptions previously described were applied.

Table 8 presents the results of the statistical tests for documented nonpharmacologic interventions across the three time periods. A positive proportional difference represents a difference in the optimal direction (as specified by the alternate hypothesis). There was an increase in the proportional differences in nonpharmacologic interventions for: Time Zero and Time Two; Time Zero to Time One; and Time One to Time Two. However, the proportional difference in nonpharmacologic interventions between Time Zero and Time One was not statistically significant.
Table 8

*Results of Statistical Tests of Significance for Documentation of Nonpharmacologic Interventions*

<table>
<thead>
<tr>
<th>Proportional Difference in Nonpharmacologic Intervention Documentation</th>
<th>Mean Diff.</th>
<th>SE Diff.</th>
<th>tc</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paired Samples t-test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time Zero to Time One</td>
<td>-.00043</td>
<td>.00051</td>
<td>-.830</td>
<td>68</td>
<td>*</td>
</tr>
<tr>
<td>Time Zero to Time Two</td>
<td>.00500</td>
<td>.00135</td>
<td>3.705</td>
<td>68</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Time One to Time Two</td>
<td>.00535</td>
<td>.00134</td>
<td>3.999</td>
<td>69</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wilcoxon Signed Ranks Test</th>
<th>Zc</th>
<th>Asymp p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Zero to Time One</td>
<td>-1.62</td>
<td>*</td>
</tr>
<tr>
<td>Time Zero to Time Two</td>
<td>2.91</td>
<td>.004</td>
</tr>
<tr>
<td>Time One to Time Two</td>
<td>3.27</td>
<td>.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sign Test</th>
<th>Exact p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Zero to Time One</td>
<td>*</td>
</tr>
<tr>
<td>Time Zero to Time Two</td>
<td>.001</td>
</tr>
<tr>
<td>Time One to Time Two</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* Note: Since the researcher hypothesized a positive change in the documentation of nonpharmacologic interventions and there was a slight decrease in nonpharmacologic interventions from Time Zero to Time One, the statistical result is an Automatic Non-rejection of the null since the evidence (data) does not support the direction hypothesized in the alternate hypothesis.

These results are of clinical importance. Again the *a priori* effect size that was set was based on evidence supported by the research literature was 20%. When examining the entire programmatic interventions the effect size for documented nonpharmacologic interventions was 34.47%. The results support the use of a programmatic intervention to increase documentation of nonpharmacologic interventions by the nursing staff.

**Nurse Characteristics**

*Research Questions Three and Four*

Research Questions Three and Four were descriptive in nature and inquired of the nurse characteristics which were found to be associated with documentation of pain assessment and nonpharmacologic pain management, respectively. These questions were answered after detailed demographic and work-related descriptions of the attending nurses were collected.
The data were then scrutinized for trends and correlation coefficients were generated for all relevant variables. Each of the nurses participated in a 30-minute educational session and completed a demographic questionnaire. Of the 54 participants, 100% completed and returned the demographic questionnaire. Demographic characteristics were collected using the Demographic Questionnaire developed by the researcher. The sample \((n = 54)\) consisted of 100% females. The different racial/ethnic groups of the participants were: 43 (79.6%) Caucasian, 10 (18.5%) African-American, and 1 (0.5%) Hispanic. The median age of the nurses was 41.5 years (mean = 39.92 years, \(SD = 11.04\)), with the youngest nurse participant being 22 years, and the oldest participant being 60 years. Educational degrees consisted of 25 (46.3%) Baccalaureate, 20 (37%) Associate, 7 (13%) Vocational, 1 (1.9%) Clinical Nurse Specialist, and 1 (1.9%) Diploma. Table 9 presents the age, years of nursing experience, years of newborn nursing experience, and newborn nursing experience in the selected site. In addition, the nurses that participated in the educational session were asked if they had any experience with the NIPS prior to working at this facility; 85.2% (46) answered no and 14.8% (8) answered yes. There was 59.3% (32) of the nurses that participated in the educational session that were full-time employees. Table 10 illustrates that there was representation from all shifts worked and the work status of the participants.

Table 9

<table>
<thead>
<tr>
<th>Demographic Characteristics of Total Sample of Nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range in Years</td>
</tr>
<tr>
<td>Age in Years</td>
</tr>
<tr>
<td>Years Nursing Experience</td>
</tr>
<tr>
<td>Newborn Nursing Experience</td>
</tr>
<tr>
<td>Newborn Experience in Selected Site</td>
</tr>
</tbody>
</table>
Table 10

**Work Characteristics of Total Sample of Nurses**

<table>
<thead>
<tr>
<th>Work Status:</th>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day Shift</td>
<td>30</td>
<td>55.5</td>
</tr>
<tr>
<td>Evening Shift</td>
<td>5</td>
<td>9.3</td>
</tr>
<tr>
<td>Night Shift</td>
<td>19</td>
<td>35.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shift Worked:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-time</td>
<td>32</td>
<td>59.3</td>
</tr>
<tr>
<td>Part-time</td>
<td>10</td>
<td>18.5</td>
</tr>
<tr>
<td>Flex/PRN</td>
<td>8</td>
<td>14.8</td>
</tr>
<tr>
<td>Agency</td>
<td>4</td>
<td>7.4</td>
</tr>
</tbody>
</table>

For the purpose of comparison, the demographics of the nurses that were present for the entire programmatic intervention were compared to those nurses who were not. Of the nurses that participated in the educational session, 53.7% (29/54) were present for all phases of the programmatic intervention. This subset of nurses (n = 29) were employees of the family care unit 1.3 years and longer. The age range of this subset of nurses was a minimum of 25 years to a maximum age of 60 years. The different racial/ethnic groups of the participants were: 22 Caucasian (75.9%); and 7 African-Americans (24.1%). The work status of these nurses includes: 14 full-time (48.3%); 8 part-time (27.6%); 5 flex/PRN (17.2%); and 2 agency (6.9%). The years of newborn nursing experience ranges from a minimum of 1.5 years to a maximum of 32 years. Of these nurses four (13.8%) answered yes to having previous experience with the NIPS prior to its introduction at this facility.

There were 25 (46.3%) of the nurses that participated in the educational intervention provided by the researcher, that were not present for all phases of implementation of the NIPS. All of these nurses have been employees of this facility for 1 year or less. The range of newborn nursing experience for this subset ranges from .08 years of experience up to a maximum of 24 years of experience. The age range of these nurses was 22 years of age to a maximum of 52 years of age. The race/ethnicity of the participants were: 21 Caucasian (84%); 3 African-American (12%); and 1 Hispanic (4%). The work status of these nurses includes: 18 full-time (72%); 2 part-time (8%), 12 flex/PRN (12%); and 2 agency (8%). Similar to the nurses that were present for the entire programmatic intervention, four (16%) of the nurses answered yes to having previous experience with the NIPS prior to being introduced to it through this facility.
Other Results

When examining the correlations between variables, there was a negative Pearson correlation ($r = -2.52$) between years of nursing experience and the total number of NIPS scores documented. Likewise, there was a negative correlation ($r = -1.50$) between the documentation of nonpharmacologic interventions and years of nursing experience. The importance of this correlation will be discussed in Chapter 5.

Conclusions

The following conclusions were drawn from the analysis of the data.

1. The programmatic intervention had a positive effect on the frequency of pain assessments documented and, specifically, in the frequency of documentations of pain assessment following circumcision, heel lance, venipuncture, and lumbar puncture procedures.

2. The programmatic intervention had a positive effect on the frequency of documentation of nonpharmacologic management of newborn pain.

Summary

This study provided statistical findings to compare the differences between the mean number of documentations of pain assessment following painful procedures, and nonpharmacologic interventions over three periods in time. In the data collected, there was an increase in the frequency of documentations of pain assessments following painful procedures, and nonpharmacologic interventions. The differences were statistically significant for the documentation of pain assessment after painful procedures and nonpharmacologic interventions between Time 0 and Time 2. Also, of interest was the frequency of routine pain assessments. The results of the study showed an increase in the documentation of routine pain assessments (Time 0 to Time 2). In addition a description of the sample of nurses that participated in phase two of the programmatic intervention was included. A discussion of the outcomes of this study will be presented in Chapter 5.
The purpose of this inquiry was to evaluate the effectiveness of a comprehensive intervention for increasing the assessment documentation of newborn pain following circumcision, heel lance, venipuncture, and lumbar puncture procedures, as well as the documentation of nonpharmacologic newborn pain management. Patient charts meeting the required inclusionary criteria were sampled through random selection and base-line data were extracted from a period of time immediately prior to the implementation of the policy change and educational intervention. Another sampling using random selection was accomplished approximately 3 months post-program implementation. The final sampling, executed similarly, and test of the program’s effectiveness occurred approximately 1 year subsequent to the program’s implementation. This chapter presents a discussion of the findings; comparison of findings to the literature; limitations; assumptions; strengths; conceptual framework; implications for nursing profession, practice, education, and administration; and recommendations for future nursing research.

**Discussion of Findings**

The overall findings of this study, following the programmatic intervention, indicate that there was an increase in documentation of pain assessment following painful procedures. The study also showed an increase in the total number of pain assessments and nonpharmacologic interventions documented in the nurses’ notes. The results of the study were both statistically significant and of practical importance. There was an increase in the mean number of pain assessments, pain assessments following painful procedures, and nonpharmacologic interventions documented.

Changes in behavior occur slowly over time. Of the nurses in this study, 50% were greater than 41 years of age. An interesting Pearson correlation ($r = -2.52$) showed that as the number of years of nursing experience increased, the total number of NIPS
documented decreased. This phenomenon can be partially explained using the principles of andragogy (Knowles, 1998). The previous experiences of adult learners can inhibit their learning process and can lead to resistance to change. Presumably, the nurses with more years of nursing experience have more life experience, which may possibly lead to more resistance to change. Other studies have found similar results that indicate an increase in knowledge does not always reflect a change in behavior. Halimaa et al. (2001) concluded that many of the nurses in their sample possessed knowledge about pain, pain assessment, and management of pain in newborns, but their actions were not consistent with their knowledge. There is another way to look at the negative correlation between mean years of nursing experience and the number of NIPS, documented using the principles of andragogy (Knowles, 1998). The nurses with less nursing experience may perceive a greater need to know, related to newborn pain management, and may be more likely to apply a new concept to practice that they perceive enhances their role as a newborn nurse.

The nurses that participated in phase two of the educational intervention were compared with other nurses in the United States. The mean age of the nurse participants in this study was 39.92 years, the average age nationally was slightly higher, with a mean of 45.2 years of age. The different racial/ethnic groups of the participants were: 79.6% Caucasian, 19% minority groups. The national racial/ethnic groups included: 88% Caucasians (non-Hispanic white) and 12% minority groups. The sample of nurse participants had a slightly higher percentage of minority nurses, which according to Spratley, Johnson, Sochalski, Fritz, and Spencer (2000) is more common in the southern United States. Educational degrees consisted of 46.3% Baccalaureate, 37% Associate, 13% Vocational, 1.9% Clinical Nurse Specialist, and 1.9% Diploma. The national average for educational degrees of registered nurses included 34.3% Associate, 32.7% Bachelors, 22.3% Diploma, and 9.6% Masters or Doctoral (Spratley et al., 2000). The sample of nurses had a higher percentage of Bachelors Degrees and Associate degrees that the national average, which may be due to the facility being a teaching hospital for two local universities, and a community college. The sample also has a considerably lower than average number of diploma nurses, this may be due to the fact that there are no Diploma programs in the area.
Relationship to Literature

The literature reviewed and presented for this study included numerous findings and recommendations related to improving pain assessment, utilizing nonpharmacologic interventions, and pain management documentation by nurses. Based on the literature review, newborn pain management documentation remains inadequate despite increased awareness and the implementation of mandates by regulatory agencies (Alexander & Manno, 2003; Bildner & Krechel, 1996; Bookbinder et al., 2002; Halimaa et al., 2001). Although this study showed an increase in documentation of the total number of pain assessments, pain assessments following painful procedures, and nonpharmacologic interventions, the results remain less than optimal. The results of this study correlated with the studies in the literature review. Gallo (2003) implemented the NIPS in a hospital in southern California. A chart review conducted 1 year after the implementation of the tool, revealed an improvement in pain assessment documentation. However, there was not 100% adherence to the policy that was implemented (Gallo, 2003). Rond et al. (2000) found that nurses documented pain intensity in the medical records a mean of 3.4 times ($SD = 4.5$) per patient. After implementation of a pain monitoring program, the mean number of pain intensity scores in the medical record increased to 5.1 ($SD = 6.8$) per patient (Rond et al., 2000). In this study there was an increase in the mean number of NIPS scores from a mean of 0.28(Time Zero) to a mean of 7.0 after the intervention (Time 2). Reyes (2003) found only 1% (3/289) of the charts reviewed in their study had a documented follow-up pain assessment. Similarly, this study revealed that for Time Zero (pre-intervention) there was only one pain assessment documented after a painful procedure, although 119 painful procedures were performed. After the programmatic intervention (Time Two) there was 21.7% (25/115) of the painful procedures documented had a follow-up documentation of pain assessment 1-2 hours post-procedure.

Limitations of the Study

Several limitations were identified for this study. The data collected from the newborn records did not include demographic data. This limited the researcher’s ability to explore further any correlation between age, race, or sex of the newborn with documentation of pain assessment and nonpharmacologic interventions by the nurses. A
similar limitation of the study is that it included all newborns in the level I nursery, which encompasses infants with a wide variety of gestational ages (35 to 40 weeks) and hospital experiences, which may alter behavioral responses to painful procedures. By knowing the demographic information of the newborn, including gestational age, it would have allowed the demographic information collected in the study to be compared with demographic data at other hospitals and would have enhanced the generalizability of the study. In addition, knowing demographic information may have aided in the identification of confounding variables related to inadequate documentation of newborn pain assessment post-painful procedures and nonpharmacologic interventions by nurses.

Nurse demographics for Time Zero and Time One were not available for comparison. Due to the implications of the Health Insurance Portability and Accountability Act (HIPAA) the researcher was not able to link documentation patterns from the medical record with the nurses that attended the educational interventions. The researcher attempted to minimize this limitation by making the educational intervention available on PowerPoint for all nurses following the one week educational intervention provided by the researcher. Again, by not having demographic information for all nurses that documented pain assessment in the medical records for Time Zero and Time One it limits the conclusions that can be drawn from the study and the researcher’s ability to address confounding variables. It also limits the researcher’s ability to examine the difference in pain management documentation by specific nurses that attended phase two of the programmatic intervention. Without linking the participants, by name, to their documentation, the researcher was unable to compare the documentation practices of those nurses who attended the educational intervention with those that did not or to compare the participants' documentation prior to the intervention to their documentation following the intervention, to evaluate change in their behavior.

Another limitation of the study is the risk of the Hawthorne Effect. Awareness of being in a pain assessment study may have altered the documentation behaviors of the nurses for Time Two. This may alter the documentation of pain assessment after painful procedures and nonpharmacologic interventions and may have resulted in an overestimation of the results of the programmatic intervention.
A final limitation of this study is that it did not evaluate the nurses’ attitudes, beliefs, and baseline knowledge of newborn pain that may have influenced their pain documentation practices. A pre- and post-test related to knowledge of pain assessment and documentation may have strengthened the study by allowing the researcher to demonstrate knowledge deficits prior to the programmatic intervention and an increase in knowledge post-intervention. A survey related to nurses’ attitudes, and beliefs would have allowed the researcher to compare the nurses’ beliefs about newborn pain management with pain assessment documentation in the medical record.

**Strengths of the Study**

The random selection of newborn records for all three time periods allows the findings to be generalized and applied to the population of newborns. This study examined changes in nurse behaviors which occur over time. Another strength of this study was that 83% (54/65) of the accessible population of nurses caring for newborns participated in phase two of the programmatic intervention. In addition, over 50% of the nurses that participated in the educational intervention were present for the entire programmatic intervention. Therefore, the demographics of the nurses are representative of the nursing population caring for newborn patients in the selected facility and compared favorably to nurses nationwide in terms of mean age, racial/ethnic groups, and educational preparation. This indicates that these nurses are representative of the larger population of nurses in the United States. This study contributes to the body of knowledge regarding documentation of newborn pain assessment and nonpharmacologic interventions, and supports the use of education to optimize pain management documentation in this vulnerable population. Furthermore, the study provides nurse researchers with a theoretical framework and research design that can be used for replication and/or further investigation.

**Assumptions**

In using documentation to assess nursing practice, an assumption is made that documentation accurately reflects nursing practice. This may be an underestimation of actual pain assessment conducted and nonpharmacologic interventions utilized. There is no way for the researcher to support or deny this assumption. However, the standard by which all nurses are guided throughout their careers in dealing with their responsibility
with legal documentation is “not documented, not done.” Therefore, there is some comfort that the documentation represents a strong portion of nurses practice. The researcher also made an assumption that the target population had knowledge deficits regarding newborn pain physiology and pain assessment tools and these deficits influence the nurses’ assessment and documentation of pain assessment in the newborns. Similarly, the researcher assumed that the nurses had knowledge deficits regarding nonpharmacologic interventions and these deficits influenced the nurses’ implementation and documentation of nonpharmacologic interventions. This study supports that the nurses had knowledge deficits regarding newborn pain management, since there was an increase in documentation of pain assessments and nonpharmacologic interventions after the educational intervention on newborn pain management. These assumptions were also supported by the research literature (AHCPR, 1992; Gallo, 2003; Halimaa et al., 2001).

The methodological assumptions of the study were related to the statistical tests chosen. The two-related samples t-test was chosen because the researcher cannot argue for independence of documentation behaviors before and after the intervention, since some of the nurses were included in the repeated samplings of charts. The other assumptions required for this test were: (a) that the population of difference-scores were normally distributed, (b) the observations (difference scores) were independent, and (c) that the sample of charts was randomly selected. Support for the analytical assumptions was discussed in Chapter 4, and the results of the nonparametric tests were reported since the reader may be more comfortable with these results, which does not require these assumptions.

**Conceptual Framework**

The framework that guided this study was a combination of Dorothea Orem’s Self-Care Deficit Theory of Nursing (2001) and the Theory of Adult Learners (Knowles, 1998). The Self-Care Deficit Theory provided the necessary elements needed for implementing changes in the documentation of the NIPS, by enhancing the nurses’ awareness of the infants’ self-care deficits and self-care demands. In the newborn population, the need for nursing is validated because the self-care agency of the neonate is not fully operative to meet his/her self-care demands, and the self-care deficits exceed the knowledge and abilities of the dependent-care agent. Tolentino (1990) theorized that
infants have signaling cues, such as changes in behavior and crying, that assist the
dependent-care agent in meeting the infant’s needs. An awareness of the neonate’s
behavioral indicators of pain can help the nurse respond to the infant’s self-care needs.

The NIPS evaluates six behavioral indicators of pain and can assist the nurse in
recognizing infants experiencing pain. The self-care demands of the infant, related to
pain, may be increased following painful procedures. Therefore, the nurse should assess
pain after painful procedures to evaluate the infant for behavioral indicators of pain. The
nurse can then utilize nonpharmacologic interventions to help meet the self-care demands
of identified infants experiencing pain. Integrating nonpharmacologic interventions into
care giving promotes the infant’s own coping abilities, and can minimize the differences
between self-care agency and self-care demands. Documentation of pain assessment and
nonpharmacologic interventions in the chart records the neonate’s unique reactions to
positive and negative stimuli. This information can be utilized by the nurse to optimize
pain management and utilization of nonpharmacologic interventions.

The study demonstrated the need for continuing education for nurses regarding
pain assessment and nonpharmacologic interventions for newborns. Utilizing the
approach of andragogy to educate nurses about pain can enhance the teaching-learning
process, can increase the receptiveness of the nurse, and can promote a positive learning
environment. An educational intervention was provided for the nurses that enhanced
their ability to interpret and respond to the signaling cues that the infant uses related to
pain. Careful attention was given to ensure that the education intervention utilized the
learning concepts described by Malcolm Knowles to educate the adult learner.
According to Knowles (1998), an andragogical approach should be utilized when
educating the adult learner.

When utilizing this approach, there are several assumptions that must be made
about adult learners: (a) they are self directed; (b) they can utilize life experiences as a
resource for learning; (c) they must perceive a need to know; and (d) they are problem-
centered and interested in immediate application of knowledge (Knowles, 1998). These
assumptions guided the design and implementation of the educational intervention
provided for the nurses. The researcher attempted to enhance the participants’ awareness
of the “need to know” in the invitational letter presented to each nurse. The letter
included the purpose of the study and described the benefits and risks of the research. The format and time obligation of the participants was also explained. Every nurse was given an invitation to participate in the educational course, and only those nurses that had a desire to participate attended the session. By presenting real life scenarios, the educator was able to aid the learner in applying the concepts to situations that occur in real life. The nurses were able to select the time and date of the educational session they wished to attend from a variety. The educator could make the assumption that the nurses that came to the educational session were motivated to learn, based on their willingness to participate in an educational intervention that was strictly voluntary.

Utilizing this model was an effective framework to guide this study. A sample of 83% (54/65) of the nurses participated in phase two of the programmatic intervention. Since this was a voluntary educational intervention, the researcher can assume, based on the principles of andragogy that the nurses that participated on a voluntary basis perceived a need to know, and were motivated to learn. The effect size (Time 0 to Time 2) for documentation of pain assessment post painful procedures was 33.25%. Likewise, the effect size for documented nonpharmacologic interventions was 34.47%. There was an increase in the mean number of pain assessments and nonpharmacologic interventions documented in the newborn record. Figure 1 is the Newborn Pain Management Model.

**Implications for Nursing**

*Profession*

Although there was an increase in the documentation of pain assessment and nonpharmacologic interventions following painful procedures, more education and follow-up is needed to improve adherence. To meet standards of best practice and to comply with the mandates of regulatory agencies, 100% adherence is required. The medical record is a legal document and nurses demonstrate professional accountability through their written documentation. Assessments and interventions that are not documented in the medical record are assumed not to have occurred.
The Newborn Pain Management Model is derived from the Self-Care Deficit Theory (Orem, 2001) and the principles of andragogy (Knowles, 1998). The two circles at the top of the model represent the self-care of the infant and the dependent-care of the parent. The circles are surrounded by dotted lines because the self-care agency of the neonate is not fully operative to meet its self-care demands, and the self-care deficits exceed the knowledge and abilities of the dependent-care agent. A reciprocal relationship is indicated by lines with an arrow head at both ends. Note the relationship between self-care agency and self-care demands is indicated with a reciprocal relationship. However, when self-care demands exceed the infant’s self care agency, a self-care deficit exists. Nurses utilize the NIPS to assess behavioral indicators of pain, which are a form of self-care agency. Nurses can utilize nonpharmacologic interventions to minimize the difference between self-care agency and self-care demands. The self-care demands of the infants related to pain may be increased after painful procedures. Therefore, pain assessment using NIPS should be conducted 1 to 2 hours post-painful procedures. The programmatic intervention increased nursing agency by providing information about pain assessment and management. The nurse contributed to the programmatic intervention by enriching the learning environment with contributions of real life scenarios. Nurses contribute information to the infant’s medical record by documenting pain assessment, interventions, and the effectiveness of those interventions. Likewise, the nurse receives information from the medical record by reviewing previous nursing documentation including the infant’s responses to negative and positive stimuli.
Nursing documentation tools should be clear and easy to use. For example, instead of documenting nonpharmacologic interventions in the nurses’ narrative notes, there should be an easy and concise method of check boxes of nonpharmacologic interventions to make it easier and more convenient for the nurses to document the interventions utilized. Furthermore, nurses must advocate for policies and practices that provide both pharmacologic and nonpharmacologic interventions for pain relief in newborns. The use of research-based pain assessments, interventions for pain relief, and the evaluation of the effectiveness of those interventions must be a priority of nurses providing care for newborn infants.

**Advanced Practice**

Advanced practice nurses must lead the challenge to promote better pain management for newborns. The Clinical Nurse Specialist (CNS) can utilize advanced practice knowledge, expert clinical and teaching skills, research abilities, and role as a change agent to implement successfully pain management policies (White, 1999). The CNS should assist in the development of policies regarding newborn pain that are based on evidenced-based research and standards of best practice. These policies should incorporate appropriate pharmacologic and nonpharmacologic pain interventions that can be utilized to optimize pain management of the newborn. The CNS can also utilize the role of educator to provide continuing education in-services for nursing staff, physicians, and other healthcare providers regarding newborn pain management (White, 1999). As this study indicates, education cannot be provided in a single lesson, but must be reinforced in an ongoing process. In addition, the accurate documentation of pain assessment must be evaluated. Therefore, periodic chart reviews must be conducted to ensure adherence to the policy and mandates. The CNS Case Managers can advocate for increased quality by collecting outcomes data for pain management for comparison with national benchmarks. In addition the CNS Case Manager can enhance awareness of newborn pain management with nurses, physicians, pharmacists, and other members of the healthcare team during multidisciplinary rounds. Not only must the CNS Case Manager be the advocate for appropriate pain management for the newborn population, but he/she must be the leader among disciplines to elevate the quality of care provided and offer evidence of improved parental satisfaction, caregiver satisfaction, and
organizational cost effectiveness. The consequence of poorly managed neonatal pain must be discussed with all the stakeholders so that everyone realizes how important the issue is.

**Education**

Nursing programs must incorporate the physiology of newborn pain, and the importance of accurate documentation of newborn pain into nursing curriculum (Halimaa et al., 2001). As this study suggests, nurses that have limited nursing experience may be more open to new pain assessment tools and pain management strategies for newborns. A very strong focus of novice nurses is always trying to prevent discomfort in every intervention they implement. They are still unsure of their own actions and want to believe their actions are bringing comfort and satisfaction to their patients. Those caring for infants are even more strongly moved to learn how to comfort them. Nursing students will not be hindered by preconceived notions or biases about newborn pain, and may perceive a greater need to know. Education about pain management should be reinforced throughout the nursing curriculum and in the clinical setting. In addition, continuing education courses regarding newborn pain management must be offered periodically for practicing nurses caring for newborns.

**Administration**

Administrators of nursing must assist in the goal of optimal pain management for newborns. This can be achieved by establishing the expectations and competencies for nurses regarding pain management documentation of the newborn. Nursing leaders should incorporate these competencies into the annual evaluations of the nurses and hold nurses accountable for the pain management of their patients. Furthermore, pain management policies and procedures must be incorporated into the orientation of new nurses. Nursing administrators are in the position to collaborate with the medical director in establishing protocols and order sets for physicians to further enhance newborn pain management.

**Recommendations for Future Research**

The replication of research strengthens the findings of studies. Therefore, similar studies should be conducted to evaluate a programmatic educational intervention to increase documentation by nurses. As previously mentioned, in order to meet the
requirements of regulatory agencies and the policy implemented by the hospital, additional educational interventions and follow-up chart reviews will need to be conducted. In addition, further research is needed that studies the long term consequences of inadequate pain management in the neonatal period. There was also limited research that used Orem’s Self-Care Deficit Theory to guide the care of the newborn. As this study illustrated, the components of the Self-Care Deficit Theory can be utilized when caring for the newborn patient. The principles of andragogy for adult learners must also continue to be researched in the healthcare setting. This includes evaluating the variables that may prevent older nurses from changing behaviors as readily as younger nurses after an educational intervention regarding newborn pain management. Furthermore, future researchers should develop and test other tools and interventions aimed at increasing documentation of pain assessment by nurses. For example, there can be implementation and evaluation of peer review groups that allow nurses to evaluate the documentation of themselves and their colleagues. More research is needed into the attitudes that influence the assessment and management of pain by nurses (Halimaa et al., 2001). A study needs to be designed which can meet HIPAA regulations in which an educational program is implemented and the participants’ actual documentation thereafter is compared to their documentation prior to the program. This is more likely to be approved if designed and conducted by the CNS or CNS Case Manager on the unit.

This study focused on nonpharmacologic interventions to alleviate pain. These interventions do not require a written order and are interventions nurses commonly use and incorporate into their daily care. More research will need to be conducted that assesses the implementation of pharmacologic pain policies for the pain management of newborns. This will require the collaboration of a multidisciplinary team including nursing, pharmacy, and physicians. The implementation of additional policies for pain management will require ongoing education for the nursing staff and physicians and chart reviews to ensure adherence to the policy.

**Summary**

This study demonstrated the effectiveness of a programmatic intervention on the assessment documentation of newborn pain as well documentation of nonpharmacologic newborn pain management following circumcision, heel lance, venipuncture, and lumbar
puncture procedures. The study supports the use of Orem’s Self Care Deficit Theory (2001) and Malcolm Knowles’ principles of andragogy (1998) as a theoretical framework to guide the study. Even though there has been increased awareness of newborn pain and the implementation of mandates by regulatory agencies to improve pain management in the newborn population, there remains a lack of documentation of accurate pain assessment and nonpharmacologic interventions to alleviate pain for newborns following painful procedures in the medical record. There is an ethical and moral obligation to newborns to manage their pain and to prevent potential long-term consequences associated with the under-treatment of newborn pain. Nurses caring for newborns must advocate for their patients and implement policies and procedures to ensure optimal pain management. Advanced practice nurses must educate nurses on an ongoing basis about pain and conduct chart reviews to ensure adherence to these policies. Ongoing education is necessary to increase pain management documentation. This study supports that nursing is on the precipice for a total change in practice and can be the catalyst for this multidisciplinary paradigm shift.
APPENDIX A

FLORIDA STATE UNIVERSITY APPROVAL LETTER
Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2763
(850) 644-8673 · FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 8/17/2004

To:
Amanda Sarvis
2156 Kinsley Lane
Tallahassee Fl 32308

Dept.: NURSING

From: John Tomkowiak, Chair

Re: Use of Human Subjects in Research
    Assessment and Documentation of Newborn Pain: An Intervention and Longitudinal
    Evaluation

The forms that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Secretary, the Chair, and two members of the Human Subjects Committee. Your project is determined to be Exempt per 45 CFR § 46.101(b) 2 and has been approved by an accelerated review process.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals, which may be required.

If the project has not been completed by 8/16/2005 you must request renewed approval for continuation of the project.

You are advised that any change in protocol in this project must be approved by resubmission of the project to the Committee for approval. Also, the principal investigator must promptly report, in writing, any unexpected problems causing risks to research subjects or others.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols of such investigations as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Protection from Research Risks. The Assurance Number is IRB00000446.

Cc: Jeanne Flannery
    HSC No. 2004.300
I understand that there are potential benefits for participating in this research project. First, my own awareness about pain management may be increased. Also, I will be providing researchers with valuable insight into pain management practices for newborns. This knowledge can assist in improving pain assessment documentation by nurses.

I understand that there is a minimal level of foreseeable risk involved in this study if I agree to participate. I might experience anxiety or guilt when reflecting on my newborn pain management practices. The nurse researcher and clinical nurse specialist will be available to discuss any emotional discomfort I may experience while participating. I am also able to stop my participation at any time I wish.

I understand that my participation is voluntary and that I may withdraw from the study at any point without penalty. I have been given the opportunity to ask questions about this study, and my questions have been answered to my satisfaction.

Any additional questions I have concerning the research study or my participation in it, before and after my consent, will be answered by Dr. Jeanne Flannery at Florida State University, School of Nursing at (850) 644-5626 or Amanda Sarvis at (850) 644-5974.

In case of inquiry or in event I have questions about my rights as a participant in the research study, I can contact the Chair of the Florida State University Human Subjects Committee through the office of the Vice President for Research at (850) 644-8633.

The nature, demands, benefits, and any risk of the project have been explained to me. I knowingly assume any risks involved. I understand that in signing this consent form, I am not waiving any legal claims, rights, or remedies.

I have read the entire informed consent form and have been offered a copy with my signature.

Participant Signature

Printed Name of Participant

Date
APPENDIX B

TALLAHASSEE MEMORIAL HOSPITAL APPROVAL LETTER
July 30, 2004

Amanda Sarvis, RN, BSN
2156 Kinsley Lane
Tallahassee, FL 32308

Dear Ms. Sarvis:

I have reviewed your proposed thesis entitled, “Assessment in Documentation of Newborn Pain: An Intervention and Longitudinal Evaluation.” I find that your study meets the criteria for an Expedited Review by the Institutional Review Board at Tallahassee Memorial. I am enclosing a HIPAA acknowledgement form and if you will please sign and return this form to us, at that time you may commence your study.

Please forward a copy of your completed thesis to the Medical Staff Office so it can be included in our file and reported to the Institutional Review Board.

Sincerely,

[Signature]

Richard I. MacArthur, M.D., MS
Vice President/Chief Medical Officer
Administrative Liaison/IRB

Enclosure
APPENDIX C

INFORMED CONSENT FORM
INFORMED CONSENT FORM

Title of Research: Assessment and Documentation of Newborn Pain: An Intervention and Longitudinal Evaluation

I freely and voluntarily, and without any element of force or coercion, consent to participate in this project. I have been informed that this project is to be conducted, as part of the degree requirements, by Amanda Sarvis, a registered nurse, who is currently enrolled in the graduate nursing program at Florida State University. The study will take place during the period of May 1, 2004, through May 1, 2005, under the guidance of Jeanne Flannery, DSN, ARNP, a Professor in the School of Nursing.

I understand that the purpose of this research project is to evaluate the effectiveness of a programmatic intervention on the frequency of documentation of pain assessment and nonpharmacologic interventions by nurses.

I understand that once I give my consent, my participation will involve attending a pain education session, and filling out a paper and pencil demographic questionnaire with general information about myself. The total time commitment will be about 45 minutes.

I understand that chart reviews will be conducted prior to and after the pain education session. The chart reviews are institutionally driven for quality improvements and my nurses’ notes will not be identified or tied to me personally. Nor is the chart review being conducted to evaluate infant condition or treatment by physicians. The chart review is designed to evaluate the frequency of nurses’ documentation of pain assessment and nonpharmacologic interventions after circumcisions, venipunctures, heel sticks, and/or lumbar punctures.

I understand that my privacy will be protected at all times. All information gathered during the course of this study will remain confidential to the extent allowed by law, and only group findings will be reported. All information will be identified by a code number, and no names will appear in any report. The data will be in a locked file cabinet in the researcher’s office until May, 2010, after which they will be destroyed. Only the researcher and the research committee will have access to the data. The results of this research may be published but my name or identity will not be revealed.

I understand that I will not be paid by the researcher to participate in this study. However, I understand that I will be permitted to attend the educational session during work hours if I choose, and I will be paid by the hospital for this time.
I understand that there are potential benefits for participating in this research project. First, my own awareness about pain management may be increased. Also, I will be providing researchers with valuable insight into pain management practices for newborns. This knowledge can assist in improving pain assessment documentation by nurses.

I understand that there is a minimal level of foreseeable risk involved in this study if I agree to participate. I might experience anxiety or guilt when reflecting on my newborn pain management practices. The nurse researcher and clinical nurse specialist will be available to discuss any emotional discomfort I may experience while participating. I am also able to stop my participation at any time I wish.

I understand that my participation is voluntary and that I may withdraw from the study at any point without penalty. I have been given the opportunity to ask questions about this study, and my questions have been answered to my satisfaction.

Any additional questions I have concerning the research study or my participation in it, before and after my consent, will be answered by Dr. Jeanne Flannery at Florida State University, School of Nursing at (850) 644-5626 or Amanda Sarvis at (850) 644-5974.

In case of inquiry or in event I have questions about my rights as a participant in the research study, I can contact the Chair of the Florida State University Human Subjects Committee thought the office of the Vice President for Research at (850) 644-8633.

The nature, demands, benefits, and any risk of the project have been explained to me. I knowingly assume any risks involved. I understand that in signing this consent form, I am not waiving any legal claims, rights, or remedies.

I have read the entire informed consent form and have been offered a copy with my signature.

________________________  
Participant Signature

____________________________  
Printed Name of Participant

____________________________  
Date
DEMOGRAPHIC QUESTIONNAIRE

1. Age in years __________
2. Ethnicity __________
3. Total years of nursing experience __________
4. Total years of newborn nursing experience __________
5. Total years of newborn nursing experience in this facility_______
6. Any experience with NIPS, prior to working at this facility? If applicable. Yes/no
7. Shift worked: (please circle)
   7a-3p      7a-7p      3p-11p      11p-7a      7p-7a      other: ______
8. Work Status: (please circle)
   Full-time   Part-time   Flex/PRN   Agency   Traveler
9. Licensure:  (please circle)
   LPN        RN, ADN     RN, BSN    ARNP      CNS      Other_______
10. Certifications: (please list)
    ____________________________________________________________
        _________________________________________________________
APPENDIX E

CHART AUDIT TOOL
<table>
<thead>
<tr>
<th>Chart</th>
<th>Total # of NIPS Scores</th>
<th>Total # of NIPS Scores &gt; 3</th>
<th>What procedure was performed?</th>
<th>Number of Procedures</th>
<th>Number of NIPS done 1-2 hours after the procedure?</th>
<th>Total # of nonpharmacologic interventions documented?</th>
<th>Number of nonpharmacologic interventions for NIPS &gt; 3</th>
<th>Nonpharmacologic Interventions Documented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chart 1</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
<tr>
<td>Chart 2</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
<tr>
<td>Chart 3</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
<tr>
<td>Chart 4</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
<tr>
<td>Chart 5</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
<tr>
<td>Chart 6</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
<tr>
<td>Chart 7</td>
<td></td>
<td></td>
<td>Circumcision</td>
<td></td>
<td></td>
<td></td>
<td>Reposition</td>
<td>Wrap &amp; swaddle</td>
</tr>
</tbody>
</table>
APPENDIX F

NEONATAL INFANT PAIN SCALE (NIPS)
### Pain Assessment Tool for Well Newborns

<table>
<thead>
<tr>
<th>Criteria Score</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facial Expression</strong></td>
<td></td>
</tr>
<tr>
<td>0 – relaxed muscles</td>
<td>restful face, neutral expression</td>
</tr>
<tr>
<td>1 – grimace</td>
<td>tight facial muscles, furrowed brow, chin</td>
</tr>
<tr>
<td><strong>Cry</strong></td>
<td></td>
</tr>
<tr>
<td>0 – no cry</td>
<td>quiet, no crying</td>
</tr>
<tr>
<td>1 – whimper</td>
<td>mild moaning, intermittent</td>
</tr>
<tr>
<td>2 – vigorous cry</td>
<td>loud scream, rising, shrill, continuous</td>
</tr>
<tr>
<td><strong>Breathing Patterns</strong></td>
<td></td>
</tr>
<tr>
<td>0 – relaxed</td>
<td>usual pattern for this infant</td>
</tr>
<tr>
<td>1 – changes in breathing</td>
<td>irregular, faster than usual, breath holding</td>
</tr>
<tr>
<td><strong>Arms</strong></td>
<td></td>
</tr>
<tr>
<td>0 – relaxed/restrained</td>
<td>no muscular rigidity, occasional random arm movement</td>
</tr>
<tr>
<td>1 – flexed/extended</td>
<td>tense, straight arms, rigid and/or rapid extension/flexion</td>
</tr>
<tr>
<td><strong>Legs</strong></td>
<td></td>
</tr>
<tr>
<td>0 – relaxed/restrained</td>
<td>no muscular rigidity, occasional random leg movement</td>
</tr>
<tr>
<td>1 – flexed/extended</td>
<td>tense, straight legs, rigid and/or rapid extension/flexion</td>
</tr>
<tr>
<td><strong>State of Arousal</strong></td>
<td></td>
</tr>
<tr>
<td>0 – sleeping / awake</td>
<td>quiet, peaceful / sleeping or alert</td>
</tr>
<tr>
<td>1 – fussy</td>
<td>restless, thrashing / asleep or awake</td>
</tr>
</tbody>
</table>
APPENDIX G

EDUCATIONAL OUTLINE
The Fifth Vital Sign:

Pain Assessment in the Neonate Population

Edited by Ana-Marie Gallo, MSN, CNS, RNC
Presented by Mandy Sirois, BSN, RN

California Assembly Bill 791
Effective January 1, 2000 implementation of the "fifth vital sign".

The fifth vital sign entails that health care professionals record a pain assessment each time that vital signs are recorded.

Pain is defined as:
"an unpleasant sensory and emotional experience that is associated with actual or potential tissue damage or described in terms of such damage."

Educating the Patient:
Discuss with patient/support person a plan for pain management.
Educate the patient how to measure her pain by rating it on a 0-10 scale. Zero defines no pain, ten defines her most severe pain.
Document patient education.

Pain Assessment in the Neonate Population

Pain Management in Infants
"Nurses must be proactive in the assessment and management of pain in hospitalized infants.
...each institution caring for newborns must ensure that all infants have access to highest level of safely administered pain relief/control"

Newborn Pain Myth #1

Infants are incapable of experiencing pain because of incomplete myelination and immaturity of their nervous system

Newborn Pain Myth #1

FACT
Clinical evidence indicates that this myth is not true.
Infants are indeed capable of experiencing pain.

10 Newborn Pain Myth #2

Infants may not experience pain because they do not exhibit discernible responses to painful procedures.

11 Newborn Pain Myth #2

Fact
Approaching pain assessment from a multidimensional perspective will yield a more accurate estimate of the infant’s pain experience than any other single physiologic or behavioral measurement.

12 Newborn Pain Myth #3

Newborns are incapable of remembering pain.

13 Newborn Pain Myth #3

Fact
Short-term behavioral changes following painful procedures in newborns suggest the possibility that early pain experience may have long-lasting effects on behavior and/or development.

14 Newborn Pain Myth #4

The threat of potential side effects in infants, associated with pain medication, are coupled with the fear of addiction.

15 Newborn Pain Myth #4

Fact
It is possible to provide adequate anesthesia, amnesia and/or analgesia to infants in most situations without any form of addiction. Generally speaking, non-pharmacological measures should be used before progressing to pharmacological agents.

16 Research

Gross movement

Withdraw from pain

Physiologic & autonomic responses

Behavioral responses
Research

Gross movement
Withdraw from pain

Physiologic and Autonomic Indicators of Pain

1. Heart rate
2. Respiratory rate
3. Vagal tone
4. Variability of heart rate and oxygen saturation
5. Blood Pressure

2. Palmar sweating
3. Transcutaneous oxygen saturation levels
4. PO2 levels
5. Intracranial pressure
6. Cortisol levels

Behavioral Indicators of Pain

Facial expression
Cry (fundamental frequency, peak spectral energy, duration, latency)
Body movements

The Neonatal Infant Pain Scale (NIPS)

A behavioral assessment tool for infants under the age responding to pain.
A measure of intensity of infant responses to painful procedure
Provides an objective measure of pain-relieving interventions and their effectiveness. The NIPS scale is objective, non-intrusive, and assesses only behavioral response to pain.

NIPS
Newborn Facial Expression:

NIPS
Newborn Cry:

NIPS
Newborn Breathing Pattern:
NIPS

Newborn Arms:

NIPS

Newborn Legs:

NIPS

Newborn State of Arousal:

NIPS

Scoring:

When to Assess for Pain:
Every time vital signs are taken and at nurses’ discretion.
1 and 2 hours after an invasive procedure (heel stick, intramuscular injection, circumcision etc.)

Documentation:

Newborn Pain Screen
Comfort measures and interventions

Appropriate Non-pharmacological Interventions
1. Reposition (place prone or side-lying)
2. Wrap and swaddle in warm blanket (provide intrauterine-like support)
3. Support skin-to-skin care
4. Reduce stimulation (environment, dim lights, quiet voice)
5. Hold and rock in vertical position
6. Light massage or stroking (avoid area of pain)
7. Pacifier (per parent consent)
8. Put to breast or feed as appropriate

Practice your Assessment

NIPS

Scoring Baby:

Conclusion
APPENDIX H

INVITATIONAL LETTER
Dear Family Care Unit Colleague,

I am a registered nurse, who is currently enrolled in the graduate nursing program at Florida State University under the guidance of Jeanne Flannery, DSN, ARNP, a Professor in the School of Nursing. I am conducting a research study to evaluate the effectiveness of a programmatic intervention on the frequency of documentation of pain assessment and nonpharmacologic interventions by nurses.

I am requesting your participation, which will involve attending a pain education session, and filling out a paper and pencil demographic questionnaire. The total time commitment will be about 45 minutes. Once the dates and times of the educational session have been scheduled the researcher will post a list of this information on the unit. Your participation in this study will be voluntary. If you choose not to participate or to withdraw form the study at any time, there will be no penalty. All information gathered during the course of this study will remain confidential to the extent allowed by law, and only group findings will be reported. All information will be identified by a code number, and no names will appear in any report. The results of the study may be published but your name will not be known.

You will not be paid by the researcher to participate in this study. However, you will be permitted to attend the educational session during work hours if you choose, and will be paid by the hospital for this time.

Any questions you have concerning the research study or your participation in it, before and after your consent, will be answered by Dr. Jeanne Flannery at Florida State University, School of Nursing at (850) 644-5626 or Amanda Sarvis at (850) 644-5974.

Sincerely,

Amanda Sarvis, BSN, RN
REFERENCES


BIографICAL SKETCH

Amanda Sarvis earned her Bachelor’s Degree in Nursing from Florida State University (FSU) in 2000 at which time she was hired as a clinical nurse in the Level I nursery at Tallahassee Memorial Hospital. In Fall, 2002, she returned to FSU to pursue her advanced degree as a Clinical Nurse Specialist Case-Care Manager. She is currently employed as the Clinical Case Manager for Women’s and Children’s Services at Tallahassee Memorial Hospital.